# TITLE 9. ENVIRONMENT

## VIRGINIA WASTE MANAGEMENT BOARD

### 9 VAC 20-120. Regulated Medical Waste Management Regulations.

Statutory Authority: § 10.1-1402 of the Code of Virginia.

Effective Date: June 19, 2002.

## Part I
## Definitions

### 9 VAC 20-120-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise. Chapter 14 (§ 10.1-1400 et seq.) of Title 10.1 of the Code of Virginia defines words and terms that supplement those in this chapter. The Virginia Solid Waste Management Regulations, 9 VAC 20-80, define additional words and terms that supplement those in the statutes and this chapter. When the statutes, as cited, and the solid waste management regulations, as cited, conflict, the definitions of the statutes are controlling.

"Act" or "regulations" means the federal or state law or regulation last cited in the context, unless otherwise indicated.

"Alternative treatment method" means a method for the treatment of regulated medical waste that is not incineration or steam sterilization (autoclaving).

"Approved sanitary sewer system " means a network of sewers serving a facility that has been approved in writing by the Virginia Department of Health, including affiliated local health departments. Such sewer systems may be approved septic tank/drainfield systems and on-site treatment systems, or they may be a part of a collection system served by an NPDES permitted treatment works.

"Associated" means two or more firms that share staff members, management, directors, and assets or engage in joint ventures. Holding companies and part owners are associated parties.

"Ash" means the residual waste material produced from an incineration process or any combustion.

"ASTM" means the American Society For Testing and Materials.

"Autoclave tape" means tape that changes color or becomes striped when subjected to temperatures that will provide sterilization of materials during treatment in an autoclave or similar device.

"Blood" means human blood, human blood components, and products made from human blood.

"Board" means the Virginia Waste Management Board.

"Body fluids" means liquid emanating or derived from humans including blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; semen and vaginal secretions; amniotic fluid; urine; saliva in dental procedures; and any other body fluids that are contaminated with blood, and any other liquids emanating from humans that may be mixed or combined with body fluids.

"Closure" means the act of securing a regulated medical waste management facility pursuant to the requirements of these regulations.

"Closure plan" means the plan for closure prepared in accordance with the requirements of this chapter.

"Commonwealth" means the Commonwealth of Virginia.

"Container" means any portable enclosure in which a material is stored, transported, treated, or otherwise handled.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other body fluids on an item or surface.

"Contingency plan" means a document setting out an organized, planned and coordinated course of action to be followed in the event of a fire, explosion, or release of regulated medical waste or regulated medical waste constituents that could threaten human health or the environment.

"CWA" means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act), 33 USC § 1251 et seq.; PL 92-500, PL 93-207, PL 93-243, PL 93-592, PL 94-238, PL 94-273, PL 94-558, PL 95-217, PL 95-576, PL 96-148, PL 96-478, PL 96-483, PL 96-510, PL 96-561, PL 97-35, PL 97-117, PL 97-164, PL 97-216, PL 97-272, PL 97-440, PL 98-45, PL 100-4, PL 100-202, PL 100-404, and PL 100-668.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy human pathogens on a surface or item to the point where they are no longer capable of transmitting disease and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the Virginia Department of Environmental Quality.

"Director" means the Director of the Department of Environmental Quality or his designee.

"Discard" means to throw away or reject. When a material is soiled, contaminated or no longer usable and it is placed in a waste receptacle for disposal or treatment prior to disposal, it is considered discarded.

"Discharge" or "waste discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of regulated medical waste into or on any land or state waters.

"Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste into or on any land or water so that such solid waste or any constituent of it may enter the environment or be emitted into the air or discharged into any waters, including ground waters.

"Disposal facility" means a facility or part of a facility at which solid waste is intentionally placed into or on any land or water, and at which the solid waste will remain after closure.

"Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

"Empty" means wastes have been removed from a container using the practices commonly employed to remove materials of that type.

"EPA" means the U.S. Environmental Protection Agency.

"Etiologic agents" means the specific organisms defined to be etiologic agents in 42 CFR 72.3. In general, etiologic agents as defined in 42 CFR 72.1 means a viable microorganism or its toxin which causes or may cause human disease.

"Federal agency" means any department, agency, or other instrumentality of the federal government, any independent agency, or establishment of the federal government including any government corporation and the Government Printing Office.

"Generate" means to cause waste to become subject to regulation. When regulated medical waste is first discarded, it must be appropriately packaged in accordance with this regulation. At the point a regulated medical waste is discarded it has been generated.

Note: Timeframes associated with storage and refrigeration are no longer linked to the "date of generation."

"Generator" means any person, by site location, whose act or process produces regulated medical waste identified or listed in Part III (9 VAC 20-120-80 et seq.) of this chapter or whose act first causes a regulated medical waste to become subject to this chapter.

"Hazardous material" means a substance or material that has been so designated under 49 Parts CFR 171 and 173.

"Hazardous waste" means any solid waste defined as a "hazardous waste" by the Virginia Hazardous Waste Management Regulations.

"Health Care Professional" means a medical doctor or nurse practicing under a license issued by the Department of Health Professions.

"Highly leak resistant" means that leaks will not occur in the container even if the container receives severe abuse and stress, but remains substantially intact.

"Highly puncture resistant" means that punctures will not penetrate the container even if the container receives severe abuse and stress, but remains substantially intact.

"Motor vehicle" means a vehicle, machine, roll off container, tractor, trailer, or semi-trailer, or any combination of them, propelled or drawn by mechanical power and used in transportation or designed for such use.

"Nonstationary health care providers" means those persons who routinely provide health care at locations that change each day or frequently. This term includes traveling doctors, nurses, midwives, and others providing care in patients' homes, first aid providers operating from emergency vehicles, and mobile blood service collection stations.

"NPDES" or "National Pollutant Discharge Elimination System" means the national program for issuing, modifying, revoking, reissuing, terminating, monitoring, and enforcing permits pursuant to §§ 307, 402, 318, and 405 of the Clean Water Act. The term includes any state or interstate program that has been approved by the Administrator of the United States Environmental Protection Agency.

"Off-site" means any site that does not meet the definition of on-site as defined in this part, including areas of a facility that are not on geographically contiguous property or outside of the boundary of the site.

"On-site" means the same or geographically contiguous property, which may be divided by public or private right-of-way, provided the entrance and exit to the facility are controlled by the owner or the operator of the facility. Noncontiguous properties owned by the same person but connected by a right-of-way that he controls and to which the public does not have access are also considered on-site property.

"Owner" means the person or persons who own a regulated medical waste management facility or part of a regulated medical waste management facility.

"Package" or "outside package" means a package plus its contents.

"Packaging" means the assembly of one or more containers and any other components necessary to assure compliance with minimum packaging requirements under VRGTHM or this chapter.

"Permit by rule" means provisions of this chapter stating that a facility or activity is deemed to have a permit if it meets the requirements of the provision.

"Permitted waste management facility" or "permitted facility" means a regulated medical waste treatment or storage facility that has received a permit in accordance with the requirements of the chapter.

"Physical construction" means excavation, movement of earth, erection of forms or structures, the purchase of equipment, or any other activity involving the actual preparation of the regulated medical waste management facility.

"Processing" means preparation, treatment, or conversion of regulated medical waste by a series of actions, changes, or functions that bring about a decided result.

"RCRA" means the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 USC § 6901 et seq.), the Hazardous and Solid Waste Amendments of 1984, and any other applicable amendments to these laws.

"Regulated medical waste" means solid wastes defined to be regulated medical wastes in Part III (9 VAC 20-120-80 et seq.) of this chapter.

"Regulated medical waste management" means the systematic administration of activities that provide for the collection, source separation, storage, transportation, transfer, processing, treatment, and disposal of regulated medical wastes whether or not such facility is associated with facilities generating such wastes or otherwise.

"Regulated medical waste management facility" means a solid waste management facility that manages regulated medical waste.

"Safe sharps program" means a program supported by a city, county, town or public authority that is intended to enhance the safe disposal of sharps discarded by private individuals.

"Sanitary sewer system" means a system for the collection and transport of sewage, the construction of which was approved by the Department of Health or other appropriate authority.

"Secondary container" means a storage device into which a container can be placed for the purpose of containing any leakage from the original container.

"Section" means a subpart of this chapter and when referred to all portions of that part apply.

"Sharps" means needles, scalpels, knives, syringes with attached needles, pasteur pipettes and similar items having a point or sharp edge or that are likely to break during transportation and result in a point or sharp edge.

"Shipment" means the movement or quantity conveyed by a transporter of a regulated medical waste between a generator and a designated facility or a subsequent transporter.

"Site" means the land or water area upon which a facility or activity is physically located or conducted, including but not limited to adjacent land used for utility systems such as repair, storage, shipping, or processing areas, or other areas incident to the controlled facility or activity.

"Solid waste" means any garbage, refuse, sludge and other discarded material, including solid, liquid, semisolid or contained gaseous material, resulting from industrial, commercial, mining and agriculture operations, or community activities, but does not include (i) solid or dissolved material in domestic sewage, (ii) solid or dissolved material in irrigation return flows or in industrial discharges which are sources subject to a permit from the State Water Control Board, or (iii) source, special nuclear, or by-product material as defined by the Federal Atomic Energy Act of 1954, as amended 42 USC §§ 2011-2284. The definition of solid waste is further clarified in the Virginia Solid Waste Management Regulations (9 VAC 20-80-140).

"Solid waste management" means the collection, source separation, storage, transportation, transfer, processing, treatment, and disposal of solid wastes or resource recovery.

"Spill" means any accidental or unpermitted discharge, leaking, pumping, pouring, emitting, or dumping of wastes or materials that, when spilled, become wastes.

"Start-up" or "cold start-up" means the beginning of a combustion operation from a condition where the combustor unit is not operating and less than 140°F in all areas.

"Storage" means the holding, including during transportation, of more than 200 gallons of waste, at the end of which the regulated medical waste is treated or stored elsewhere.

"Training" means formal instruction, supplementing an employee's existing job knowledge, designed to protect human health and the environment via attendance and successful completion of a course of instruction in regulated medical waste management procedures, including contingency plan implementation, relevant to those operations connected with the employee's position at the facility.

"Transfer facility" means any transportation related facility including loading docks, parking areas, storage areas, and other similar areas where shipments of regulated medical waste are held during the normal course of transportation.

"Transportation" or "transport" means the movement of regulated medical waste by air, rail, highway, or water.

"Transport vehicle" means any vehicle used for the transportation of cargo.

"Vector" means a living animal, insect or other arthropod that may transmits an infectious disease from one organism to another.

"VRGTHM" means Virginia Regulations Governing the Transportation of Hazardous Materials promulgated by the Virginia Waste Management Board as authorized by §§ 10.1-1450 through 10.1-1454 of the Code of Virginia.

"Waste management facility" means all contiguous land and structures, other appurtenances, and improvements on them used for treating, storing, or disposing of waste.

"Waste management unit" means any unit at a treatment or storage facility that possesses a permit, or that has received regulated medical waste (as defined in this chapter) at any time, including units that are not currently active.

## Part II
## Legislative Authority and General Information

**9 VAC 20-120-20. (Repealed.)**

**9VAC20-120-30. Purpose of regulations.**

The purpose of these regulations is to establish standards and procedures pertaining to regulated medical waste management in this Commonwealth in order to protect the public health and public safety, and to enhance the environment and natural resources.

**9 VAC 20-120-40. Administration of regulations.**

A. The Virginia Waste Management Board promulgates and enforces regulations that it deems necessary to protect the public health and safety, the environment, and natural resources.

B. The Virginia Waste Management Board and/or the director may enforce the provisions of this chapter utilizing all applicable procedures under the law.

**9 VAC 20-120-50. Applicability of regulations.**

A. This chapter applies to all persons who manage regulated medical waste, own or operate regulated medical waste management facilities or allow regulated medical waste management facilities to be operated on their property in this Commonwealth, to those who seek approval to engage in these activities and to all persons who manage regulated medical wastes, except those specifically exempted or excluded elsewhere in this chapter.

B. All existing regulated medical waste management facilities must comply with this chapter.

C. By December 16, 2002, all permitted regulated medical waste management facilities will place in their operating record updated design and operation information in accordance with the requirements of 9 VAC 20-120-730.

D. All existing regulated medical waste management facilities in possession of a permit issued by the director are now deemed to be operating under the provisions of permit by rule. Any modification, transfer, violation or termination of the permit will be in accordance with the procedures specified for permit by rule.

**9 VAC 20-120-60. Severability.**

A. The board intends that these regulations be severable, so that if any provision or part of these regulations is held invalid, unconstitutional or inapplicable to any person or circumstances, such invalidity, unconstitutionality or inapplicability shall not affect or impair the remaining provisions of these regulations and their application.

B. This chapter supersedes and replaces all previous regulations of the Waste Management Board to the extent that those prior regulations conflict with the regulations presented here. Where there does not exist a conflict between the prior regulations and those presented here, no replacement shall be deemed to occur and the prior regulations shall remain. This chapter supersedes and replaces in their entirety the following previous rules of the board: "Infectious Waste Management Regulations," effective May 2, 1990; "Regulated Medical Waste Management Regulations," effective June 30, 1993; and "Regulated Medical Waste Management Regulations," effective June 29, 1994.

C. This chapter shall remain in effect unless amended, rescinded, or otherwise altered by the Virginia Waste Management Board. Where there appears to be a conflict between this chapter and other regulations adopted at a future date, and such future regulations do not specifically clarify this chapter, this chapter shall be controlling.

D. These regulations are completely separate from all federal or local governmental regulations.

**9 VAC 20-120-70. Relationship to other bodies of regulation.**

A. The Solid Waste Management Regulations (9 VAC 20-80) address other requirements for regulated medical waste management. Any regulated medical waste management facility must also conform to any applicable sections of the solid waste management regulations issued by the board and any special solid waste management regulations such as those defining financial assurance requirements. If there is a conflict between the details of regulations here and the others, this chapter is controlling.

B. Regulated medical waste management facility must also comply with any applicable sections of the Hazardous Waste Management Regulations (9 VAC 20-60) issued by the department. If there is a conflict between the details of regulations here and the hazardous waste management regulations, the latter regulations are controlling.

C. Intrastate shipment of hazardous materials is subject to the Regulations Governing the Transportation of Hazardous Materials (9 VAC 20-110) of the department. If there is a conflict between the details of regulations here and the hazardous materials transportation regulations, the latter are controlling.

D. Generators of regulated medical waste and regulated medical waste management facilities may be subject to the general industry standard for occupational exposure to bloodborne pathogens in 16 VAC 25-90-1910.1030 (29 CFR 1910.1030).

E. Persons transporting regulated medical waste are subject to the federal hazardous material transportation requirements in 49 CFR 171 through 178.

F. If there is a conflict between the regulations here and adopted regulations of another agency of the Commonwealth, the provisions of these regulations are set aside to the extent necessary to allow compliance with the regulations of the other agency. If neither regulation controls, the more stringent standard applies.

G. Nothing here either precludes or enables a local governing body to adopt ordinances. Compliance with one body of regulation does not insure compliance with the other, and, normally, both bodies of regulation must be complied with fully.

## Part III
## Identification and Listing of Regulated Medical Waste

**9 VAC 20-120-80. Purpose and scope.**

A. This part contains general provisions in 9 VAC 20-120-80 and 9 VAC 20-120-90, provisions for recycling of regulated medical wastes in 9 VAC 20-120-100, provisions for conditional exemption from regulation in 9 VAC 20-120-110, a description of persons exempt in all or in part from the regulations in 9 VAC 20-120-120, a description of waste and materials excluded from consideration in these regulations in 9 VAC 20-120-130, and the definition of regulated medical waste in 9 VAC 20-120-140 and 9 VAC 20-120-150.

B. Wastes identified in this part are regulated medical wastes and are subject to this chapter, the Virginia Regulated Medical Waste Management Regulations.

C. The basic definition of solid waste appears in 9 VAC 20-120-10 along with other pertinent definitions and shall be referred to for the exact meaning of the terms used. Additional detailed descriptions of regulated medical wastes, exclusions and listings required to arrive at the proper classification of wastes are the subject of this part.

**9 VAC 20-120-90. Materials rendered nonregulated.**

Wastes that were once regulated and managed in accord with this chapter, and that are no longer regulated medical waste, shall be managed in accordance with such other regulations of the board that apply.

1. Packaging. Treated waste that was once regulated, but is no longer regulated medical waste, shall not be packaged as regulated medical waste. Solid waste packaged as regulated medical waste is regulated medical waste.

2. Recordkeeping. If the solid waste is no longer regulated medical waste because of treatment, the generator and the permitted facility shall maintain a record of the treatment for three years after treatment to include the date and type of treatment, type and amount of regulated medical waste treated, and the individual operating the treatment unit. Records for on-site treatment and shipping papers from commercial carriers for off-site treatment shall be maintained by the generator. Records for off-site treatment and shipping papers for off-site treatment shall be maintained by all permitted facilities. Generators or permitted facilities with more than one unit may maintain a centralized system of recordkeeping. All records shall be available for review by the department upon request.

**9 VAC 20-120-100. Recycled materials.**

A. Untreated regulated medical wastes shall not be used, reused, or reclaimed.

B. Wastes that have been treated in accord with these regulations are no longer regulated medical waste and may be used, reused, or reclaimed in accordance with the provisions of the Virginia Solid Waste Management Regulations (9 VAC 20-80).

C. Bed linen, instruments, medical care equipment and other materials that are routinely reused for their original purpose are not subject to these regulations until they are discarded and are a solid waste. These items do not include reusable carts or other devices used in the management of regulated medical waste (See 9 VAC 20-120-260).

**9VAC20-120-110. Documentation of claims that materials are not solid wastes or are conditionally exempt from regulation.**

Respondents in actions to enforce this chapter who raise a claim that a certain material is not a solid waste, or is conditionally exempt from regulation, shall demonstrate that they meet the terms of the exclusion or exemption. In doing so, they shall provide appropriate documentation to demonstrate that the material is not a waste, or is exempt from regulation.

**9 VAC 20-120-120. Exemptions to the regulations.**

Exemptions to this chapter include:

1. Composting of sewage sludge at the sewage treatment plant of generation and not involving other solid wastes.

2. Land application of wastes regulated by the State Board of Health, the State Water Control Board, the Virginia Department of Agriculture and Consumer Services, or any other state agency with such authority.

3. Wastewater treatment or pretreatment facilities permitted by the State Water Control Board by a NPDES permit.

4. Management of hazardous waste as defined and controlled by the Virginia Hazardous Waste Management Regulations to the extent that any requirement of those regulations is in conflict with regulations here.

**9 VAC 20-120-130. Exclusions.**

A. Materials described in this section may be partially or totally excluded from these regulations because they are not solid waste, not regulated medical waste or are regulated medical waste the board excludes from this chapter.

B. The following materials are not solid wastes for the purposes of this part:

1. Domestic sewage, including wastes that are not stored and are disposed of in a sanitary sewer system (with or without grinding);

2. Any mixture of domestic sewage and other wastes that pass through a sewer system to a wastewater treatment works permitted by the State Water Control Board or the State Department of Health;

3. Human remains under the control of a licensed physician or dentist, when the remains are being used or examined for medical purposes and are not solid wastes;

4. Human remains properly interred in a cemetery or in preparation by a licensed funeral director or embalmer for such interment or cremation; and

5. Dead or diseased animals subject to regulation by the Virginia Department of Agriculture and Consumer Services.

C. The following solid wastes are not regulated medical wastes:

1. Meat or other food items being discarded because of spoilage or contamination, and not included in 9 VAC 20-120-150.

2. Garbage, trash, and sanitary waste from septic tanks and sewage holding tanks that has been generated at any of the following locations: single or multiple residences, hotels, motels, bunkhouses, ranger stations, crew quarters, campground, picnic grounds and day-use recreation areas, except for regulated medical waste resulting from the provision of professional health care services on the premises, provided that all medical sharps discarded at those locations are placed in an opaque container with a high degree of puncture resistance and labeled "do not recycle, medical sharps" or otherwise managed in accordance with a local "safe sharps" program before being mixed with other wastes or disposed.

3. Used products for personal hygiene, such as diapers, facial tissues and sanitary napkins, underpads and adult incontinence products, unless a health care professional has determined these items to be regulated medical wastes in accordance with 9 VAC 20-120-140.

4. The following discarded items, when they are empty: urine collection bags and tubing, suction canisters and tubing, IV solution bags and tubing, colostomy bags, ileostomy bags, urostomy bags, plastic fluid containers, enteral feeding containers and tubing, hemovacs, and urine specimen cups, unless the items are subject to regulation under 16 VAC 25-90-1910.1030 (29 CFR 1910.1030) or comparable state or federal standard.

5. The following discarded items: urinary catheters, suction catheters, plastic cannula, IV spikes, nasogastic tubes, oxygen tubing and cannula, ventilator tubing, enema bags and tubing, enema bottles, thermometer probe covers, irrigating feeding syringes, and bedpans/urinals, unless the items are subject to regulation under 16 VAC 25-90-1910.1030 (29 CFR 1910.1030) or comparable state or federal standard.

6. Items such as bandages, gauze, or cotton swabs or other similar absorbent materials unless at any time following use they are saturated or would release human blood or human body fluids in a liquid or semiliquid state if compressed. Items that contain or that are caked with dried human blood or human body fluids and are capable of releasing these materials during handling are regulated medical waste. An item would be considered caked if it could release flakes or particles when handled.

**9VAC20-120-140. Characteristics of regulated medical waste.**

A solid waste is a regulated medical waste if it meets either of the two criteria of this section:

1. Any solid waste, as defined in this chapter is a regulated medical waste if it is suspected by the health care professional in charge of being capable of producing an infectious disease in humans. A solid waste shall be considered to be capable of producing an infectious disease if it has been or is likely to have been contaminated by an organism likely to be pathogenic to healthy humans, such organism is not routinely and freely available in the community, and if such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease. If the exact cause of a patient's illness is unknown, but the health care professional in charge suspects a contagious disease is the cause, the likelihood of pathogen transmission shall be assessed based on the pathogen suspected of being the cause of the illness.

2. Any solid waste that is not excluded from regulation is a regulated medical waste if it is listed in 9VAC20-120-150.

**9 VAC 20-120-150. Lists of controlled regulated medical wastes.**

In addition to wastes described by the characteristics set forth in 9 VAC 20-120-140, each solid waste or solid waste stream on the following lists is subject to this chapter, unless exempted in 9 VAC 20-120-120 or excluded in 9 VAC 20-120-130.

1. Cultures and stock of microorganisms and biologicals. Discarded cultures, stocks, specimens, vaccines and associated items likely to have been contaminated by them are regulated medical wastes if they are likely to contain organisms likely to be pathogenic to healthy humans. Discarded etiologic agents are regulated medical waste. Wastes from the production of biologicals and antibiotics likely to have been contaminated by organisms likely to be pathogenic to healthy humans are regulated medical wastes.

2. Human blood and human body fluids. Wastes consisting of human blood or human body fluids or items contaminated with human blood or human body fluids.

3. Tissues and other anatomical wastes. All human anatomical wastes and all wastes that are human tissues, organs, or body parts are regulated medical waste.

4. Sharps. Sharps likely to be contaminated with organisms that are pathogenic to healthy humans, and all needles, syringes with attached needles, suture needles, and scalpels are regulated medical wastes. This includes sharps generated through veterinary practice.

5. Animal carcasses, body parts, bedding and related wastes. When animals are intentionally infected with organisms likely to be pathogenic to healthy humans for the purposes of research, in vivo testing, production of biological materials or any other reason; the animal carcasses, body parts, bedding material and all other wastes likely to have been contaminated are regulated medical wastes when discarded, disposed of or placed in accumulated storage.

6. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any regulated medical waste.

7. Any solid waste contaminated by or mixed with regulated medical waste.

## Part IV
## General Requirements

**9 VAC 20-120-160. Permit required.**

No person who is subject to this chapter shall treat, store, or dispose of regulated medical waste without a permit from the department to engage in those activities. Any person required to have a permit for the management of regulated medical waste shall submit an application for a permit in accord with Part X (9 VAC 20-120-680 et seq.) of this chapter, with the exception that certain facilities deemed to have an on-site permit by rule in accordance with 9 VAC 20-120-180.

**9 VAC 20-120-170. Exemptions from permitting.**

A. The holding of regulated medical waste on loading docks or areas designated for loading shall not require an on-site permit by rule or a permit under Part X (9 VAC 20-120-680 et seq.) of this chapter if:

1. The regulated medical wastes are packaged, marked, and labeled for transport in accordance with applicable requirements of 9 VAC 20-120-210 D.

2. The facility merely facilitates transportation and does not involve holding of regulated medical waste for more than 24 hours.

3. No more than 25% of the regulated medical waste at the loading dock is generated off-site.

4. While regulated medical waste is present, the area is secure from unauthorized access, and means are provided to prevent damage to the packaging by the elements or other factors.

B. Facilities generating 100 gallons per week or more of regulated medical waste shall not be required to hold an on-site permit by rule for storage or a permit for storage under Part X of this chapter if:

1. A designated storage area is provided for all areas of the facility accumulating in excess of 200 gallons of regulated medical waste. Designated storage areas shall meet the special requirements for storage facilities in Part V (9 VAC 20-120-330 et seq.) of this chapter.

2. All regulated medical waste stored in a designated storage area is properly packaged in accordance with the provisions of 9 VAC 20-120-210 and labeled in accordance with the provisions of 9 VAC 20-120-220.

3. While regulated medical waste is in storage, the first date the RMW is placed in storage is affixed to the outer packaging.

4. No more than 25% of the regulated medical waste received at the facility is generated off-site.

5. Regulated medical waste is not treated on-site.

C. Facilities generating less than 100 gallons per week of regulated medical waste shall not be required to hold an on-site permit by rule for storage or a permit for storage under Part X of this chapter or maintain records as required under 9 VAC 20-120-310 if:

1. Regulated medical waste is not held on-site in quantities greater than 200 gallons.

2. Regulated medical waste is accumulated and held in a safe and secure manner ensuring the waste cannot spill, or contact workers or the general public.

3. When regulated medical waste is ready to be discarded, the generator complies with the provisions for loading docks or areas designated for loading in 9 VAC 20-120-170 A.

4. Regulated medical waste is not treated on-site.

D. If a facility does not meet the above requirements for the storage of regulated medical waste, that facility is required to obtain an on-site permit by rule for on-site storage in accordance with the provisions of 9 VAC 20-120-180.

**9 VAC 20-120-180. Persons qualifying for an on-site permit by rule.**

Qualifying facilities are deemed to operate under a permit for regulated medical waste management activities and their owners or operators are not required to comply with the permit issuance procedures of Part X (9 VAC 20-120-680 et seq.) of this chapter. While persons who own or operate qualifying facilities are not subject to Part X or required to have a written permit from the department for those qualifying facilities, they are subject to this chapter and all other parts thereof. If a person owns or operates a regulated medical waste management unit that does not qualify for an on-site permit by rule, that person must comply with Part X and all other parts of this chapter for those units, without regard to the presence of any other units on the site that are operated under a permit by rule. Only those units that are in complete compliance with all the following conditions are qualified and considered to be under an on-site permit by rule for their operation, and no on-site permit by rule shall exist for a facility failing to fulfill any of the following conditions:

1. The facility and all regulated medical waste activities are in compliance with all parts of this chapter except Part X.

2. More than 75% (by weight, in a calendar year) of all regulated medical waste that is stored, treated or disposed of by the facility is generated on-site.

3. No regulated medical waste is transported from or received by the facility without being properly packaged and labeled in accordance with this chapter. Facilities storing regulated medical waste will indicate the first date that the waste was placed in storage date on the outer packaging of the regulated medical waste.

4. The activities at the facility do not involve the placing of regulated medical waste directly into or on the land.

5. The owner or operator of the facility has notified the director in writing that the facility is operating under an on-site permit by rule. The notice shall give the name of the facility; the mailing address of the facility; the location address of the facility; the type of business the facility serves; the type of facilities (treatment, storage, transportation, disposal) involving regulated medical waste; and the name, address and telephone number of the responsible party indicated on the disclosure statement as required in subdivision 7 of this section.

6. The owner or operator of the facility has submitted to the director a certification from the local governing body (city, county, or town in which the facility is to be located) stating, without qualifications, conditions, or reservations, that the location and operation of the facility are consistent with all applicable ordinances.

7. The owner or operator of the facility has submitted to the director appropriate Key Personnel Disclosure Statements.

8. The facility will be operated by an individual certified by the Board of Waste Management Facility Operators.

**9 VAC 20-120-190. Financial assurance requirements.**

The department has adopted and will maintain a separate regulation, the Financial Assurance Regulations for Solid Waste Facilities, which shall be applicable in all parts to regulated medical waste management facilities. Nothing in this chapter governing regulated medical waste management shall be considered to delete or alter any requirements of the department as set out in Financial Assurance Regulations for Solid Waste Facilities.

**9 VAC 20-120-200. Responsibility for packaging and labeling.**

A. The generator of regulated medical waste is responsible for the packaging and labeling of regulated medical wastes. As a bag or container becomes full, it must be sealed, labeled and managed as described in this chapter. Contractors or other agents may provide services to the generator, including packaging and labeling of regulated medical waste, however, no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the regulated medical waste as required by this chapter.

B. No person shall receive for transportation, storage or treatment any regulated medical waste that is not packaged and labeled in accordance with this chapter. Contractors or other agents may package or repackage regulated medical wastes to comply with this chapter, if the packaging or repackaging is performed on-site where the regulated medical waste was generated and no transportation, storage, treatment or disposal occurs prior to the packaging or repackaging. Nothing in this section shall prevent the proper repackaging and further transportation of regulated medical waste that has spilled during transportation.

**9 VAC 20-120-210. Packaging prior to storage, treatment or transport.**

All regulated medical waste shall be packaged as follows:

1. When regulated medical wastes are discarded, they shall be placed in containers meeting the requirements of the standards for occupational exposure to bloodborne pathogens in the general industry standard in 16 VAC 25-90-1910.1030. The general industry standard requires the packaging to be closable, constructed to prevent leakage, labeled with the biohazard symbol, and closed to prevent spillage during handling. Upon being placed in storage, red bags shall be used for the packaging of all regulated medical waste except as provided in subdivision 2 of this section. Packaging shall be labeled as provided for in 9 VAC 20-120-220.

2. Contaminated sharps shall be placed directly in containers as required by the general industry standards in 16 VAC 25-90-1910.1030. The containers shall be labeled as provided for in 9 VAC 20-120-220.

3. As bags and containers become full, they shall be sealed such that no waste materials can leak.

4. Prior to transporting regulated medical waste, waste will be packaged for transportation in accordance with the standards of 49 CFR Part 173 or packaged in accordance with an exemption approved by the United States Department of Transportation.

**9 VAC 20-120-220. Labeling requirements.**

Waste packaged under subdivisions 1 or 2 of 9 VAC 20-120-210 shall be labeled. The label shall be securely attached to or printed on packaging. The label may be a tag securely affixed to the package. Indelible ink shall be used to complete the information on the label. The label and the information provided on the label must be clearly legible. The following information shall be included:

1. The name, address and business telephone number of the generator.

2. "Regulated Medical Waste" in large print.

3. The Biological Hazard Symbol.

**9 VAC 20-120-230. Etiological agents.**

All etiological agents, as defined in 49 CFR Parts 171 through 178, that are transported must be packaged and labeled as described in 49 CFR Parts 171 through 178.

**9 VAC 20-120-240. Sharps.**

Sharps must be placed directly into puncture resistant containers as required by the general industry standards in 16 VAC 25-90-1910.1030(d)(4)(iii)(A).

**9 VAC 20-120-250. Protection of packagers.**

Persons packaging regulated medical waste shall wear appropriate items of personal protective equipment.

**9 VAC 20-120-260. Special requirements for reusable containers.**

Regulated medical waste may be conveyed in reusable carts or containers under the following conditions:

1. The waste in the cart or container is packaged and labeled fully in accordance with 9 VAC 20-120-210 through 9 VAC 20-120-240.

2. Immediately following each time a reusable cart or container is emptied and prior to being reused it is thoroughly cleaned with detergent or general purpose disinfectant.

3. When reusable carts or containers containing regulated medical waste are used for off-site transport, all aspects of the cart or container management shall comply with federal Department of Transportation Hazardous Material Regulations 49 CFR Parts 171 to 178, as applicable.

**9 VAC 20-120-270. Spill containment and cleanup kit.**

All regulated medical waste management facilities are required to keep a spill containment and cleanup kit within the vicinity of any area where regulated medical wastes are managed, and the location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting regulated medical wastes are required to carry a spill containment and clean up kit in the vehicle whenever regulated medical wastes are conveyed. The kit shall consist of at least the following items:

1. Material designed to absorb spilled liquids. The amount of absorbent material shall be that having a capacity, as rated by the manufacturer, of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or 10 gallons, whichever is less.

2. One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream at a distance. The disinfectant shall be hospital grade and effective against mycobacteria.

3. Enough red plastic bags to enclose 150% of the maximum load accumulated or transported (up to a maximum of 500 bags), that meet the applicable requirements of 49 CFR Part 173 or an exemption approved by the United States Department of Transportation. These bags shall be large enough to overpack any box or other container normally used for regulated medical waste management by that facility.

4. Appropriate personal protective equipment.

5. For vehicles only, a first aid kit, fire extinguisher, boundary marking tape, lights and other appropriate safety equipment.

**9 VAC 20-120-280. Containment and cleanup procedures.**

Following a spill of regulated medical waste or its discovery, the following procedures shall be implemented:

1. Take appropriate precautions to ensure personnel do not come into contact with any contaminants by wearing appropriate personal protective equipment.

2. Repackage spilled waste in accordance with the packaging requirements in 9 VAC 20-120-210.

3. Transport any regulated medical waste by a transporter registered in accordance with the provisions of 9 VAC 20-120-480, Registration of transporters.

4. Clean and disinfect any areas having been contacted by regulated medical wastes. Materials used to decontaminate the area will be disinfectants effective against mycobacteria.

5. Take necessary steps to replenish containment and cleanup kit.

**9 VAC 20-120-290. Closure requirements.**

When a unit that has been used for regulated medical waste management is to cease operations involving regulated medical wastes, it shall be thoroughly cleaned and disinfected. All regulated medical waste shall be disposed of in accord with this chapter, and items of equipment shall be decontaminated.

**9 VAC 20-120-300. Methods of treatment and disposal.**

A. All regulated medical waste must be incinerated, sterilized by steam, or treated by a method as described in Part VII (9 VAC 20-120-520 et seq.), VIII (9 VAC 20-120-580 et seq.), or IX (9 VAC 20-120-630 et seq.) of this chapter.

B. No regulated medical waste shall be disposed of in a solid waste landfill or other solid waste management facility. Upon authorized treatment and management in accord with this chapter, the solid waste or its ash is not regulated medical waste and may be disposed of at any landfill or other solid waste management facility permitted to receive municipal solid waste or garbage, provided the disposal is in accordance with the Solid Waste Management Regulations, 9 VAC 20-80, and other applicable regulations and standards.

C. Regulated medical waste in closed bags or containers shall not be compacted or subjected to violent mechanical stress; however, after it is fully treated and it is no longer regulated medical waste, it may be compacted in a closed container. Nothing in this section shall prevent the puncturing of containers or packaging immediately prior to permitted treatment in which grinding, shredding, or puncturing is integral to the process units; however, all grinding, shredding and puncturing shall be done with safe and sanitary methods. Nothing in this section shall prevent the use of devices that grind, shred or compact to reduce volume at the point of generation. Devices will be constructed in a manner that prevents employee exposure to the waste, contains any aerosol or mist that may be caused by the process, and treats or filters any air evacuated from the chamber during processing. These devices may be employed at the point of generation and prior to enclosing the regulated medical waste in plastic bags and other required packaging; however, the waste remains regulated medical waste. Appropriate means must be employed to appropriately protect workers and contain the waste when unloading regulated medical wastes from such a device.

**9 VAC 20-120-310. Recordkeeping requirements.**

A. Unless a generator is exempt from this requirement under the provisions of 9 VAC 20-120-170 C, generators and regulated medical waste management facilities that manage regulated medical waste shall maintain the following records and assure that they are accurate and current:

1. A list of the members of any committee for the management of infection control for the facility, their address, their phone numbers and the period of their membership.

2. The date, persons involved and short description of events in each spill of more than 32 gallons of regulated medical waste or one quart of regulated medical waste consisting of free liquid.

3. A notebook or file containing the adopted policies and procedures of the facility for dealing with regulated medical wastes.

4. A log of all special training received by persons involved in regulated medical waste management.

5. A log of regulated medical waste received from off-site, the generator, the amount and its storage and receipt dates. Records shall be maintained for a period of three years and be available for review.

B. All regulated medical waste management facilities shall maintain the following records and assure that they are accurate and current:

1. A signed certificate for each load received in which the generator affirms that the load does not contain hazardous waste (including cytotoxic medications) or radioactive materials, except as provided in 9 VAC 20-120-320; or

2. A signed and effective contract, inclusive of all loads received from a generator, in which the generator affirms that all loads will not contain hazardous waste (including cytotoxic medications) or radioactive materials, except as provided in 9 VAC 20-120-320.

**9VAC20-120-320. Management of radioactive materials.**

The United States Nuclear Regulatory Commission (USNRC) has established regulations under Title 10 of the Code of Federal Regulations for the management of radioactive materials. The Virginia Department of Health has established other requirements in accordance with Title 32.1 of the Code of Virginia. No regulated medical waste containing radioactive materials, regardless of amount or origin, shall be treated unless its management and treatment are in full compliance with these two bodies of regulations and are deemed by both regulations not to represent a threat to public health and the environment.

## Part V
## Special Requirements for Storage Facilities

**9 VAC 20-120-330. Application.**

The requirements of this part apply only to areas of storage where more than 200 gallons of regulated medical waste are accumulated, including storage of regulated medical waste during transportation and at incinerator, steam sterilization and other treatment and disposal facilities. This part applies to areas used to transfer a load of regulated medical waste from one vehicle to another during transportation, or park a vehicle containing regulated medical waste during transportation for 24 hours or more. This part also applies to areas that are exempt from permitting requirements as specified in 9 VAC 20-120-170 B, which includes designated on-site storage areas. Regulated medical waste holding areas exempt from the requirements of this part are discussed in 9 VAC 20-120-170 A and C.

**9 VAC 20-120-340. Sanitation.**

All areas used to store regulated medical waste must be clean and impermeable to liquids. Carpets and floor coverings with cracks or gaps shall not be used in storage area. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement. Vectors shall be controlled.

**9VAC20-120-350. Access.**

All areas used to store regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste.

**9 VAC 20-120-360. Temperature control and storage period.**

Any regulated medical waste stored for more than seven days must be refrigerated, stored in an ambient temperature between 35° and 45°F (2° and 7°C). If the material is stored away from the site of generation and the time in storage is unknown, the regulated medical waste must be refrigerated. No regulated medical waste shall be stored for more than 15 days at the site of generation. Procedures shall be provided to ensure that the above storage timeframes are met. The date that the waste is first placed in storage will be provided on any outer packaging while the waste is in storage.

**9 VAC 20-120-370. Drainage and ventilation.**

All floor drains shall discharge directly to an approved sanitary sewer system. All ventilation shall discharge so as to minimize human exposure to the effluent. Storage, transport and transfer to, from, and between vehicles shall be under a cover or packaged in a container that protects the waste from the elements and over a floor or bermed pavement that will contain leaks and spills of liquid from the waste. No requirement for cover, floor, or pavement shall be construed if the activity is transient in nature, such as in the case of spill cleanup or weekly collection of waste packages from professional offices for transport.

**9 VAC 20-120-380. Facilities for management of reusable carts or containers.**

Waste managed in reusable carts or containers shall meet the special requirements for reusable containers in 9 VAC 20-120-260.

**9 VAC 20-120-390. Container management.**

Persons loading, unloading, or handling containers of regulated medical waste shall wear appropriate personal protective equipment.

## Part VI
## Special Requirements for Transportation

**9VAC20-120-400. Application.**

The requirements of this part apply to all transportation of regulated medical waste.

**9 VAC 20-120-410. Sanitation.**

Surfaces of equipment used to transport regulated medical waste must be clean and impermeable to liquids, if those areas are involved with the management of the waste. Carpets and floor coverings with cracks or gaps shall not be used. Vectors shall be controlled. All trucks and equipment used to transport regulated medical waste must be thoroughly cleaned with detergent or hospital grade disinfectant before being used for any other purpose and prior to any transfer of ownership. Any areas of trucks or equipment that are visibly contaminated, or that become contaminated as a result of a spill, will be immediately decontaminated in accordance with 9 VAC 20-120-280 A 4.

**9 VAC 20-120-420. Access.**

All vehicles and equipment used in the transportation of regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste.

**9 VAC 20-120-430. Temperature control and storage period.**

Any regulated medical waste that is stored for more than seven days must be refrigerated and maintained in an ambient temperature between 35° and 45°F (2° and 5°C). Any vehicle parked 24 hours or more during transport will be considered a storage facility subject to the requirements of Part V (9 VAC 20-120-330 et seq.) of this chapter. No storage during transport will be allowed without a permit issued in accordance with the procedures in Part X (9 VAC 20-120-680 et seq.) of this chapter.

**9 VAC 20-120-440. Drainage.**

Storage, transport and transfer to, from, and between vehicles shall be under a cover or in a container that protects the waste from the elements and over a floor or bermed pavement that will contain leaks and spills of liquid from the waste. All drainage shall discharge directly to or through a holding tank to an approved sanitary sewer system. No requirement for cover, floor, or pavement shall be construed if the activity is transient in nature, such as in the case of spill cleanup or weekly collection of waste packages from professional offices for transport.

**9 VAC 20-120-450. Packaging and labeling.**

No person shall transport or receive for transport any regulated medical waste that is not packaged and labeled in accord with Part IV (9 VAC 20-120-160 et seq.) of this chapter.

**9 VAC 20-120-460. Management of spills of regulated medical waste.**

A. All vehicles transporting regulated medical wastes are required to carry a spill containment and cleanup kit in the vehicle as specified in 9 VAC 20-120-270, whenever regulated medical wastes are conveyed.

B. Following a spill of regulated medical waste or its discovery, the procedures specified in 9 VAC 20-120-280 shall be implemented.

**9 VAC 20-120-470. Loading and unloading.**

Persons loading and unloading transportation vehicles with regulated medical waste shall wear appropriate personal protective equipment.

**9 VAC 20-120-480. Registration of transporters.**

A. Prior to transporting any regulated medical waste within the Commonwealth, all transporters must register with the Department of Environmental Quality. Registration shall consist of filing the data specified in subsection B of this section, in written form, and the department will issue a registration number to the transporter. No regulated medical waste shall be transported until the registration number is issued. Transporter shall notify the generator of the waste of his registration number when he collects the waste.

B. Data to be submitted by persons wishing to register as a transporter of regulated medical waste shall be as follows:

1. Name of the person or firm.

2. Business address and telephone number of person or firm. Include headquarters and local office.

3. Make, model and license number of each vehicle to be used to transport regulated medical waste within the Commonwealth.

4. Name, business address and telephone number of each driver who will operate in the Commonwealth.

5. Areas (counties and cities) of the Commonwealth in which the transporter will operate.

6. a. Any person or firm other than reported in subdivision 1 of this subsection that is associated with the registering firm or any other name under which that person or firm does business.

b. Any other person or firm using any of the same vehicles and operators.

7. The name and phone number of a person who may be contacted in the event of an accident or release.

8. A copy of the signed certification statement as follows:

I, (Full Name of Chief Executive), am chief executive officer of (Legal Name Of Firm) and do hereby affirm that all the information provided in this application is correct to the best of my knowledge; and I further affirm that neither this firm, any antecedent firm to this firm, or any of the officers of this or antecedent firms has been convicted of a felony in any state.

C. Within 30 calendar days following the change of any data in subsection B of this section, the transporter shall notify the department of that change. Failure to notify the department nullifies the registration and invalidates the registration number. When the transporter changes legal name, corporate ownership, or the chief executive officer, he shall notify the department within 30 days of such a change. Upon receiving such a notification, the department will revoke the old registration and reissue a new registration based on the new information.

D. Use of a false or invalid registration number is prohibited.

Note: All filings of data and requests for registration number and issuance of a registration number shall be in writing.

**9VAC20-120-490. Transport by mail.**

Transport of regulated medical waste by the United States Postal Services that fully complies with 39 CFR 111 shall be considered to be transportation by a registered transporter and in compliance with this chapter if:

1. The generator maintains a complete and legible copy of the manifest or mail disposal service shipping record for a period of three years (Note: disposer's certification and other tracking items must be completed and shown on the copy);

2. The addressee is a facility permitted by all the appropriate agencies of the Commonwealth of Virginia or the host state; and

3. No package may be more than 35 pounds by weight.

**9 VAC 20-120-500. Transport using reusable carts or containers.**

A. No reusable carts or containers that have been used to manage regulated medical waste may be transported unless they meet the provisions of 9 VAC 20-120-260 which requires cleaning of the cart.

B. Reusable carts or containers used to transport regulated medical waste must be sealed, highly puncture resistant, and highly leak resistant. They shall conform in all respects to 49 CFR Parts 172 through 178 for containers and transport of "regulated medical waste."

**9VAC20-120-510. [Reserved]**

## Part VII
## Special Requirements for Incineration

**9VAC20-120-520. Application.**

The requirements of this part apply to all facilities that incinerate regulated medical waste.

**9 VAC 20-120-530. Performance standards.**

A. All incinerators for regulated medical waste shall maintain the following level of operational performance at all times:

1. Operational temperature and retention time. Whenever regulated medical wastes are incinerated, all the regulated medical waste shall be subjected to a burn temperature of not less than 1,400°F (760°C) for a period not less than one hour. For all incinerators, gases generated by the combustion shall be subjected to a temperature of not less than 1,800°F (982°C) for a period of one second or more. For certain incinerators, gases generated by the combustion shall be subjected to a temperature of not less than 2,000°F (1,094°C) for a period of two seconds or more under separate requirements of the State Air Pollution Control Board. Except at start-up, interlocks or other process control devices shall prevent feeding of the incinerator unless the required conditions are achieved.

2. Loading and operating controls. The incinerator shall have interlocks or other process control devices to prevent feeding of the incinerator until the conditions in subdivision A 1 of this section are achieved. Such devices may have an override for cold start-up. In the event low temperatures occur, facilities shall have automatic auxiliary burners that are capable of maintaining the secondary chamber temperature at the minimum of 1,800°F.

3. Monitoring. There shall be continuous monitoring and recording of primary and secondary chamber temperatures. Monitoring data shall be retained for a period of three years.

4. Waste destruction efficiency. All combustible regulated medical waste shall be converted by the incineration process into ash that is not recognizable as to its former character.

B. The incinerator shall be permitted under regulations of the State Air Pollution Control Board and be in compliance with the regulations of that body.

**9 VAC 20-120-540. Analysis and management of the ash product; procedure; results and records; disposition of ash; ash storage.**

A. Once every eight hours of operation of a continuously fed incinerator and once every batch or 24 hours of operation of a batch fed incinerator, a representative sample of 250 milliliters of the bottom ash shall be collected from the ash discharge or the ash discharge conveyer. Samples collected during 1,000 hours of operation or quarterly, whichever is more often, shall be thoroughly mixed and seven random portions of equal volume shall be composited into one sample for laboratory analysis. This sample shall be tested in accord with the methods established by the Virginia Hazardous Waste Management Regulations for determining if a solid waste is a hazardous waste. Also, the sample shall be tested for total organic carbon content.

At incinerators equipped with air pollution control devices that remove and collect incinerator emissions control ash or dust, this ash shall be held separately and not mixed with bottom ash. Once every eight hours of operation of a continuously fed incinerator and once every batch or 24 hours of operation of a batch fed incinerator, a representative sample of 250 milliliters of the air pollution control ash or dust shall be collected from the pollution control ash discharge. Air pollution control ash or dust samples collected during 1,000 hours of operation or quarterly, whichever is more often, shall be thoroughly mixed and seven random portions of equal volume shall be composited into one sample for laboratory analysis. This sample shall be tested in accord with the methods established by the Virginia Hazardous Waste Management Regulations for determining if a waste is a hazardous waste.

B. A log shall document the ash sampling, to include the date and time of each sample collected; the date, time and identification number of each composite sample; and the results of the analyses, including laboratory identification. Results of analyses must be returned from the laboratory and recorded within four weeks following collection of the composite sample. The results and records described in this part shall be maintained for a period of three years, and shall be available for review.

C. If a waste ash is found to be hazardous waste (based on a sample and a confirmation sample) the waste ash shall be disposed of as a hazardous waste in accord with the Virginia Hazardous Waste Management Regulations. If ash is found not to be hazardous waste by analysis, it may be disposed of in a solid waste landfill that is permitted to receive garbage, municipal solid waste or incinerator ash, provided the disposal is in accordance with the Solid Waste Management Regulations, 9 VAC 20-80. If the ash is found to be hazardous waste, the operator shall notify the Director of the Department of Environmental Quality within 24 hours. No later than 15 calendar days following, the permittee shall submit a plan for treating and disposing of the waste on hand at the facility and all unsatisfactorily treated waste that has left the facility. The permittee may include with the plan a description of the corrective actions to be taken to prevent further unsatisfactory performance. No ash subsequently generated from the incinerator waste stream that was found to be hazardous waste shall be sent to a nonhazardous solid waste management facility in the Commonwealth without the express written approval of the director.

D. Air pollution control ash and bottom ash shall be held separately and not mixed; however, once both are determined not to be hazardous waste, they may be combined and disposed of as other solid waste. Throughout the storage of the untested material it shall be kept in covered highly leak resistant containers. It should be held until the generator determines whether the ash waste is hazardous waste. Areas where untested material containers are placed must be constructed with a berm to prevent runoff from that area.

E. Regulated medical waste treated in compliance with Part VII (9 VAC 20-120-520 et seq.), VIII (9 VAC 20-120-580 et seq.) or IX (9 VAC 20-120-630 et seq.) of this chapter shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

**9VAC20-120-550. Compliance with other parts of this chapter.**

In general, incinerator facilities shall comply with all other parts of this chapter. The site of the incinerator facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9VAC20-120-270 and 9VAC20-120-280. Regulated medical wastes that are or will be incinerated in accordance with this chapter are not required to be shredded or ground.

**9 VAC 20-120-560. Unloading operations.**

Persons loading and unloading transportation vehicles with regulated medical waste shall wear appropriate personal protective equipment.

**9VAC20-120-570. [Reserved]**

## Part VIII
## Special Requirements for Steam Sterilization

**9VAC20-120-580. Application.**

The requirements of this part apply to all steam sterilizers (autoclaves) that sterilize regulated medical waste.

**9 VAC 20-120-590. Performance standards.**

All sterilizers for regulated medical waste shall maintain the following level of operational performance at all times:

1. Operational temperature and detention. Whenever regulated medical wastes are treated in a steam sterilizer, all the regulated medical waste shall be subjected to the following operational standards (at 100% steam conditions and all air evacuated):

a. Temperature of not less than 250°F for 90 minutes at 15 pounds per square inch of gauge pressure;

b. Temperatures of not less than 272°F for 45 minutes at 27 pounds per square inch of gauge pressure; or

c. Temperatures of not less than 320°F for 16 minutes at 80 pounds per square inch of gauge pressure.

Equivalent combinations of operational temperatures, pressure and time may be approved by the director if the installed equipment has been proved to achieve a reliable and complete kill of all microorganisms in regulated medical waste at design capacity. Written requests for approval of an equivalent standard shall be submitted to the director. Complete and thorough testing shall be fully documented, including tests of the capacity to kill B. stearothermophilus. Longer steam sterilization times are required when a load contains a large quantity of liquid.

2. Operational controls and records.

a. Steam sterilization units shall be evaluated under full loading for effectiveness with spores of B. stearothermophilus no less than once per month.

b. A log shall be kept at each steam sterilization unit that is complete for the preceding three-year period. The log shall record the date, time and operator of each usage; the type and approximate amount of regulated medical waste treated; the dates and results of calibration; and the results of effective testing described in subdivision 2 a

of this section. Where multiple steam sterilization units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs shall be retained for three years and be available for review.

c. Except as described in subdivision 2 d of this section, regulated medical waste shall not be compacted or subjected to violent mechanical stress before steam sterilization; however, after it is fully sterilized it may be compacted in a closed container.

d. Except as provided in 9 VAC 20-120-550, 9 VAC 20-120-600 E or 9 VAC 20-120-650 D, regulated medical waste shall be ground or shredded into particles that are no larger than an approximate size of 0.75 inches in any dimension. If size reduction takes place prior to treatment, it shall occur in a closed unit immediately preceding the treatment unit. Size reduction following treatment must occur within 24 hours of leaving the treatment unit. Transfer from a grinder or shredder to or from a treatment unit shall be under forced draft ventilation that removes fumes from the operations area to a safe discharge.

e. All process units for the preparation or treatment of regulated medical waste shall be in closed vessels under a negative pressure atmospheric control that filters all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with an efficiency of 99.97% of 0.3 microns. Air and gases which have themselves been sterilized by the process are not required to pass through a filter.

**9VAC20-120-600. Disposal of treated wastes.**

A. Solid waste that has been steam sterilized and managed in compliance with these regulations is no longer regulated medical waste and is solid waste. Steam sterilized solid waste may be compacted.

B. All shredded or ground solid waste that has been steam sterilized shall be placed in opaque plastic bags and sealed. The bags may not be red in color. Where bulk sterilization is used and the solid waste is compacted or immediately placed in closed bulk solid waste management containers, which are more than 64 gallons in volume, the repackaging of the solid waste in bags is not required.

C. Regulated medical waste that has been treated must also be ground or shredded in accordance with 9VAC20-120-590 2 or packaged and labeled in accordance with subsection E of this section.

D. Regulated medical waste treated in compliance with Part VII, Part VIII or Part IX shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

E. Steam sterilization facilities in operation on July 1, 1994, and small scale processes providing treatment in accordance with this part of no more than 100 pounds of regulated medical waste per day (monthly average) are not required to shred or grind the waste. Facilities that do not grind or shred the waste must seal the treated waste in an orange plastic bag and securely attach a tag or label with the following message in indelible ink and legible print of a 21-point or greater typeface:

"The generator certifies that this waste has been treated in accordance with the Virginia Regulated Medical Waste Management Regulations and is no longer regulated medical waste.

Treated: (include date treatment performed)

Generator: (include name, address and telephone number of generator)."

**9VAC20-120-610. Compliance with other parts of this chapter.**

In general, sterilizer facilities shall comply with all other parts of this chapter. The site of the sterilizer facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9VAC20-120-270 and 9VAC20-120-280.

**9VAC20-120-620. [Reserved]**

## Part IX
## Special Requirements for Alternative Treatment

**9VAC20-120-630. Application.**

The requirements of this part apply to all alternative treatment methods that treat regulated medical waste.

**9 VAC 20-120-640. Performance standards.**

All alternative treatment facilities for regulated medical waste shall maintain the following level of operational performance at all times:

1. Operational controls and records. The following requirements apply to all alternative treatment facilities.

a. Except as provided in 9 VAC 20-120-550, 9 VAC 20-120-600 E or 9 VAC 20-120-650 D, regulated medical waste shall be ground or shredded into particles that are no larger than an approximate size of 0.75 inches in any dimension. If size reduction takes place prior to treatment, it shall occur in a closed unit immediately preceding or following the treatment unit. Size reduction following treatment must occur within 24 hours of leaving the treatment

unit. Transfer from a grinder or shredder to or from a treatment unit shall be under forced draft ventilation that removes fumes from the operations area to a safe discharge.

b. Alternative treatment units shall be evaluated under full loading for effectiveness with spores of B. stearothermophilus or B. subtilis no less than once per month (See 9 VAC 20-120-910 B).

c. A log shall be kept at each alternative treatment unit that is complete for the preceding three year period. The log shall record the date, time and operator; the type and approximate amount of solid waste treated; and the dates and results of calibration and testing. Where multiple alternative treatment units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs and all performance parameter recordings shall be retained for three years and be available for review.

d. Except as described in 9 VAC 20-120-300 C and subdivision 1 a of this section, regulated medical waste shall not be compacted or subjected to violent mechanical stress before treatment. After it is fully treated it may be compacted in a closed container in a safe and sanitary manner.

e. All process units for the preparation or treatment of regulated medical waste shall be in closed vessels under a negative pressure atmospheric control that filters all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with efficiency of 99.97% for 0.3 microns.

2. Special requirements by type of treatment. Facilities shall comply with the following treatment requirements for the specific technology employed. Each treatment unit shall be preceded by grinding or shredding in accordance with subdivision 1 a of this section.

a. Dry heat treatment.

(1) Any treatment unit employing dry heat as the main treatment process shall subject all the regulated medical waste to:

(a) A temperature of no less than 480°F for no less than 30 minutes ;

(b) A temperature of no less than 390°F for no less than 38 minutes; or

(c) A temperature of no less than 355°F for no less than 60 minutes.

(2) No treatment unit employing dry heat as the main treatment process shall have a treatment chamber capacity greater than 1.0 cubic feet in volume.

(3) Each treatment unit shall be equipped to sense, display and continuously record the temperature of the treatment chamber.

b. Microwave treatment.

(1) Microwaving treatment shall incorporate pretreatment by shredding and steam injection or induction.

(2) Any treatment unit employing microwave radiation as the main treatment process shall subject all the solid waste to a temperature of no less than 203°F for no less than 25 minutes.

(3) Microwave radiation power of the treatment process shall be at least six units each having a power of 1,200 watts or the equivalent power output.

(4) Each microwave treatment unit shall be equipped to sense, display and continuously record the temperature at the start, middle and end of the treatment chamber.

(5) Process temperatures at the exposure chamber entry and exit and the waste flow rate shall be continuously monitored, displayed, and recorded.

c. Chlorination.

(1) Any treatment unit employing chlorination as the main treatment process shall subject all the solid waste to a solution whose initial free residual chlorine concentration is not less than 3,000 milligrams per liter for no less than 25 minutes.

(2) The free chlorine residual of the solid waste slurry after treatment shall be maintained at 200 milligrams per liter. The treated solid waste stream shall be equipped to continuously analyze, display, and record free chlorine residual concentration. Interval sampling every two minutes or less may be substituted for continuous analysis.

d. Other alternative treatment technologies. All alternative treatment technologies approved by the director shall conform to the requirements of this part and any additional requirements the director shall impose at the time of approval.

(1) Any person who desires to use a treatment technology other than those described in subdivisions 2 a, 2 b, and 2 c of this section, or Part VII (9 VAC 20-120-520 et seq.) or Part VIII (9 VAC 20-120-580 et seq.) of this chapter shall petition the director for a review under 9 VAC 20-120-860 and 9 VAC 20-120-870.

(2) If the director finds that the technology and application is in accord with Article 3 (9 VAC 20-120-900 et seq.) of Part XI of this chapter, he may consider the facility for permitting.

(3) The director may issue a public notice that an applicant has demonstrated compliance of a process with 9 VAC 20-120-910 through 9 VAC 20-120-950 and consider 9 VAC 20-120-960 in a separate review.

**9VAC20-120-650. Disposal of treated wastes.**

A. Regulated medical waste that has been treated by an alternate treatment technique and managed in compliance with this chapter is no longer regulated medical waste and is solid waste. Treated solid waste may be compacted.

B. All regulated medical waste that has been treated shall be placed in opaque plastic bags and sealed. The bags may not be red in color. Where bulk treatment is used and the solid waste is compacted and immediately placed in closed bulk solid waste management containers, which are more than 64 gallons in volume, the repackaging of the treated solid waste in bags is not required.

C. Regulated medical waste treated in compliance with Part VII, Part VIII or Part IX shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

D. Small scale processes providing treatment of no more than five pounds per day (monthly average) of regulated medical waste in accordance with this part are not required to shred or grind the waste. Small scale facilities that do not grind or shred the waste must seal the treated waste in an orange plastic bag and securely attach a tag or label with the following message in indelible ink and legible print of a 21-point or greater typeface:

"The generator certifies that this waste has been treated in accordance with the Virginia Regulated Medical Waste Management Regulations and is no longer regulated medical waste.

Treated: (include date treatment performed)

Generator: (include name, address and telephone number of generator)."

**9VAC20-120-660. Compliance with other parts of this chapter.**

In general, alternative treatment facilities shall comply with all other parts of this chapter. The site of the treatment facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9VAC20-120-270 and 9VAC20-120-280 of this chapter.

**9VAC20-120-670. [Reserved]**

## Part X
## Permit Application and Issuance Procedures

**9 VAC 20-120-680. Scope.**

This part of the chapter describes procedures for obtaining a permit for the transfer, treatment or storage of regulated medical waste, unless specifically excluded by these regulations or under a permit by rule as defined in 9 VAC 20-120-160, 9 VAC 20-120-170, and 9 VAC 20-120-180. Owners and operators of regulated medical waste management units shall have permits during the active life (including the closure periods) of the unit. An applicant may be considered to have a permit or a permit may be terminated for one or more units at a facility without simultaneously affecting all of the units at the facility.

**9 VAC 20-120-690. Applicability; exemptions from permit requirements; off-site permits by rule; experimental facility permits; variances.**

A. Except for on-site permit by rule facilities described in Part IV (9 VAC 20-120-160 et seq.) of this chapter, no person shall construct, operate or modify a regulated medical waste management facility in this Commonwealth without a permit issued by the director in accordance with this part. Notwithstanding the above, the management of materials excluded under Part III (9 VAC 20-120-80 et seq.) of this chapter or conditionally exempt under Part III shall not require a permit.

B. Each regulated medical waste management facility permit shall be limited to one site and shall be nontransferable between sites.

C. A new permit is required when there is:

1. Any new regulated medical waste management facility; or

2. Any change in design or process of a regulated medical waste management facility that will, in the opinion of the director, result in a substantially different type of facility.

D. The owner or operator of the following facilities shall be deemed to have a regulated medical waste management facility permit notwithstanding any other provisions of Part X (9 VAC 20-120-680 et seq.) of this chapter, if all the conditions listed are met:

1. The owner or operator of a storage facility or transfer station:

a. Notifies the director of his intent to operate such a facility and provides to the department documentation required under 9 VAC 20-120-710 B;

b. Provides the director with a certification that the facility meets the standards of Part V (9 VAC 20-120-330 et seq.) of this chapter;

c. Furnishes to the director a certificate signed by a registered professional engineer that the facility has been designed and constructed in accordance with the standards of Part V;

d. Submits to the director an operational plan describing how the standards of Part V will be met and provides the operational information required in 9 VAC 20-120-730;

e. Submits to the director a closure plan describing how the standards of 9 VAC 20-120-290 will be met;

f. Submits to the director the proof of financial responsibility if required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70); and

g. Submits to the director the results of the public participation effort conducted in accordance with the requirements contained in 9 VAC 20-120-690 D 4.

2. The owner or operator of an incineration or other treatment facility:

a. Notifies the director of his intent to operate such a facility and provides to the department documentation required under 9 VAC 20-120-710 B;

b. Provides the director with a certification that the facility meets the standards of Part VII (9 VAC 20-120-520 et seq.), VIII (9 VAC 20-120-580 et seq.), or IX (9 VAC 20-120-630 et seq.) of this chapter;

c. Furnishes to the director a certificate signed by a registered professional engineer that the facility has been designed and constructed in accordance with the standards of Part VII, VIII, or IX of this chapter;

d. Submits to the director an operational plan describing how the standards of Part VII, VIII, or IX will be met, and provides the operational information required in 9 VAC 20-120-730;

e. Submits to the director a closure plan describing how the standards of 9 VAC 20-120-290 will be met;

f. Submits to the director the proof of financial responsibility if required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70); and

g. Furnishes to the director a copy of the facility permit issued for air pollution control of any regulated point source discharges at the facility.

3. Use of materials in a manner constituting disposal. (Reserved)

4. Public participation.

a. Before the initiation of any construction at the facility under 9 VAC 20-120-690 D 1 or 9 VAC 20-120-690 D 2, the owner or operator shall publish a notice in a major local newspaper of general circulation informing the public that he intends to construct and operate a facility eligible for an off-site permit by rule. The notice shall include:

(1) A brief description of the proposed facility;

(2) A statement that the purpose of the public participation is to acquaint the public with the technical aspects of the facility and how the standards and the requirements of this chapter will be met;

(3) Announcement of a 30-day comment period, in accordance with 9 VAC 20-120-690 D 4 d, and the name and address of the owner's or operator's representative where comments shall be sent;

(4) Announcement of the date, time, and place for a public meeting held in accordance with 9 VAC 20-120-690 D 4 c; and

(5) Location where copies of the documentation to be submitted to the department in support of the off-site permit by rule notification and any supporting documents can be viewed and copied.

b. The owner or operator shall place a copy of the documentation and support documents in a location accessible to the public in the vicinity of the proposed facility.

c. The owner or operator shall hold a public meeting not earlier than 15 days after the publication of the notice required in 9 VAC 20-120-690 D 4 a and no later than seven days before the close of the 30-day comment period. The meeting shall be held to the extent practicable in the vicinity of the proposed facility.

d. The public shall be provided 30 days to comment on the technical and the regulatory aspects of the proposal. The comment period will begin on the date the owner or operator publishes the notice in the local newspaper.

5. Upon receiving the certifications and other required documents and after conducting a completeness review, the director will acknowledge their receipt and inform the owner or operator of the status of the submittal. If the applicant's submission is administratively incomplete, the letter will state that the facility will not be considered to have an off-site permit by rule until the missing certifications or other required documentation is submitted. At the time of the initial receipt or at a later date, the director may require changes in the documents designed to assure compliance with the standards of Parts V, VI, VII, VIII and IX of this chapter, if applicable. Should such changes not be accomplished by the facility owner or operator, the facility will not be deemed to have a regulated medical waste management facility permit.

6. An off-site permit by rule may not be transferred by the permittee to a new owner or operator. However, when the property transfer takes place without proper closure, the new owner shall notify the department of the sale and fulfill all the requirements contained in 9 VAC 20-120-690 D 1 through 9 VAC 20-120-690 D 3 with the exception of those dealing with the financial assurance. Upon presentation of the financial assurance proof required by 9 VAC 20-70-10 et seq. by the new owner, the department will release the old owner from his closure and financial responsibilities and acknowledge existence of the new off-site permit by rule in the name of the new owner.

7. The owner or operator of a facility operating under an off-site permit by rule may modify its design and operation by furnishing the department a new certificate prepared by the professional engineer and a new operational plan. Whenever modifications in the design or operation of the facility affect the provisions of the approved closure plan, the owner or operator shall also submit an amended closure plan. Should there be an increase in the closure costs, the owner or operator shall submit a new proof of financial responsibility as required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70).

8. In the event that a facility operating under an off-site permit by rule violates any applicable siting, design and construction, or closure provisions of Part V, VII, VIII, or IX of this chapter, the owner or operator of the facility will be considered to be operating an unpermitted facility and shall be required to close under 9 VAC 20-120-290, 9 VAC 20-120-710 and 9 VAC 20-120-750.

9. The director shall terminate off-site permit by rule and shall require closure of the facility whenever he finds that:

a. As a result of changes in key personnel, the requirements necessary for an off-site permit by rule are no longer satisfied;

b. The applicant has knowingly or willfully misrepresented or failed to disclose a material fact in his disclosure statement, or any other report or certification required under this chapter, or has knowingly or willfully failed to notify the director of any material change to the information in the disclosure statement;

c. Any key personnel has been convicted of any of the crimes listed in § 10.1-1409 of the Code of Virginia, punishable as felonies under the laws of the Commonwealth or the equivalent of them under the laws of any other jurisdiction; or has been adjudged by an administrative agency or a court of competent jurisdiction to have violated the environmental protection laws of the United States, the Commonwealth or any other state and the director determines that such conviction or adjudication is sufficiently probative of the permittee's inability or unwillingness to operate the facility in a lawful manner; or

d. The operation of the facility is inconsistent with the facility's operations manual and the operational requirements of the regulations.

E. The director may issue an experimental facility permit for any regulated medical waste treatment facility that proposes to utilize an innovative and experimental regulated medical waste treatment technology or process for which permit standards for such experimental activity have not been promulgated under Part VII, VIII or IX of this chapter. Any such permit shall include such terms and conditions as will assure protection of human health and the environment. Such permits shall:

1. Provide for the construction of such facilities based on the standards shown in Part V, VII, VIII, or IX, as necessary;

2. Provide for operation of the facility for no longer than one calendar year unless renewed as provided elsewhere in this chapter;

3. Provide for the receipt and treatment by the facility of only those types and quantities of regulated medical waste that the director deems necessary for purposes of determining the efficiency and performance capabilities of the technology or process and the effects of such technology or process on human health and the environment; and

4. Include such requirements as the director deems necessary to protect human health and the environment (including, but not limited to, requirements regarding monitoring, operation, closure and remedial action), and such requirements as the director deems necessary regarding testing and providing of information to the director with respect to the operation of the facility.

For the purpose of expediting review and issuance of permits under this subsection, the director may, consistent with the protection of human health and the environment, modify or waive permit application and permit issuance requirements in Parts V, VII, VIII or IX, except that there may be no modification or waiver of regulations regarding local certification, disclosure statement requirements, financial responsibility or of procedures regarding public participation.

No experimental permit may be renewed more than three times. Each such renewal shall be for a period of not more than one calendar year.

F. The director may grant a variance in accordance with the procedures in Part XI (9 VAC 20-120-840 et seq.) of this chapter from any regulation contained in this part to a permittee, provided the requirements of Part X are met.

**9 VAC 20-120-700. Permit conditions.**

The director may include conditions in any permit that he finds necessary to protect public health or the environment or to ensure compliance with this chapter.

**9 VAC 20-120-710. Notice of intent.**

A. Any person who proposes to establish a new regulated medical waste management facility, or modify an existing regulated medical waste management facility, shall submit a permit application to the department, using the procedures set forth in 9 VAC 20-120-690 and other pertinent sections of this part.

B. To initiate the permit application process, any person who proposes to establish a new regulated medical waste management facility ("regulated medical waste management"), or modify an existing regulated medical waste management facility, or to amend an existing permit shall file a notice of intent with the director stating the desired permit or permit amendment, the precise location of the proposed facility, and the intended use of the facility. The notice shall be in letter form and be accompanied by the information described in 9 VAC 20-120-720.

No application shall be deemed complete unless it is accompanied by a disclosure statement for all key personnel as provided by DEQ Forms DISC-01 and DISC-02.

No application for a permit for a regulated medical waste management facility shall be considered complete unless the notice of intent is accompanied by a certification (DEQ Form Certificate-01) from the governing body of the county, city, or town in which the facility is to be located stating that the location and operation of the facility are consistent with all applicable ordinances. No certification shall be required for the application for an amendment or modification of an existing permit. For the convenience of the regulated community, a Request for Local Government Certification, DEQ Form CERT-01, is provided.

If the location and operation of the facility is stated by the local governing body to be consistent with all its ordinances, without qualifications, conditions, or reservations, the applicant will be notified that he may submit his application for a permit.

**9 VAC 20-120-720. Submission requirements.**

A. The information provided in this section shall be included in the submission of a notice of intent as required in 9 VAC 20-120-710 unless otherwise specified in this section.

B. A letter will be provided stating the type of facility for which the permit application is made and the certification required in subsection F of this section and all pertinent information and attachments required by this section.

C. A key map delineating the general location of the proposed facility shall be prepared and attached as part of the application. The key map shall be plotted on a seven and one-half minute United States Geological Survey topographical quadrangle. The quadrangle shall be the most recent revision available, shall include the name of the quadrangle and shall delineate a minimum of one mile from the perimeter of the proposed facility boundaries. One or more maps may be utilized where necessary to insure clarity of the information submitted.

D. A near-vicinity map shall be prepared and attached as part of the application. The vicinity map shall have a minimum scale of one inch equals 200 feet (1 inch = 200'). The vicinity map shall delineate an area of 500 feet from the perimeter of the property line of the proposed facility. The vicinity maps may be an enlargement of a United States Geological Survey topographical quadrangle or a recent aerial photograph. The vicinity map shall depict the following:

1. All homes, buildings or structures including the layout of the buildings that will comprise the proposed facility;

2. The boundaries of the proposed facility;

3. The limits of the actual waste management areas within the boundaries of the proposed facility, if applicable;

4. Lots and blocks taken from the tax map for the site of the proposed facility and all contiguous properties;

5. The base flood plain, where it passes through the map area; or, otherwise, a note indicating the expected flood occurrence period for the area;

6. Existing land uses and zoning classification;

7. All water supply wells, springs or intakes, both public and private;

8. All utility lines, pipelines or land based facilities (including mines and wells); and

9. All parks, recreation areas, dams, historic areas, wetlands areas, monument areas, cemeteries, wildlife refuges, unique natural areas or similar features.

E. A copy of the lease or deed (showing page and book location) or certification of ownership of the site. The department will not consider an application for a permit from any person who does not demonstrate legal control over the site for the period of the permit life.

F. A statement signed by the applicant indicating that he has sent written notice to all adjacent property owners or occupants that he intends to develop a regulated medical waste management facility on the site. A copy of the notice and the names and addresses of those to whom the notices were sent will also be provided.

**9 VAC 20-120-730. Operational information.**

A. A narrative will be provided outlining the details of the design/operational capacities of the facility, emergency contingency information and daily operation of the facility as follows:

1. The narrative shall identify the project title; engineering consultants; site owner, licensee and operator; site life and capacity; municipalities, industries and collection and transportation agencies served; and waste types to be disposed. It shall also identify any exemptions desired by the applicant.

2. The narrative shall include the following information:

a. The rated capacity of the facility, in both tons per day and tons per hour;

b. The expected short-term and projected future long-term daily loadings;

c. The designation of normal loading, unloading and storage areas, including capacities in cubic yards and tons. Description of the time such areas can be practically used, based on expected short-term daily loadings;

d. The designation of emergency loading, unloading, storage or other actions to be taken when facility system down time exceeds 24 hours;

e. The designation of alternate treatment areas or plans for transfer of stored waste in the event facility system down time exceeds 72 hours.

3. The narrative will discuss the generation of process residues to include the following:

a. The expected daily quantity of waste residue generated;

b. The proposed ultimate disposal location for all facility-generated waste residues including, but not limited to, treated waste, ash residues and by-pass material, residues resulting from air pollution control devices, and the proposed alternate treatment or disposal locations for any unauthorized waste types, which may have been unknowingly accepted. The schedule for securing contracts for the treatment or disposal of these waste types at the designated locations shall be provided;

c. A descriptive statement of any materials use, reuse, or reclamation activities to be operated in conjunction with the facility, either on the incoming regulated medical waste or the outgoing residue.

4. A discussion of the proposed onsite and off-site transportation system intended to service vehicles hauling waste to the facility for processing, and vehicles removing reclaimed materials and or process residues from the facility. Onsite parking, access and exit points, and the mechanisms or features that will be employed to provide for an even flow of traffic into, out of, and within the site, shall be identified.

5. A detailed analysis shall be made of the financial responsibility for the time of site closing.

B. The operations manual shall provide the detailed procedures describing actions taken by facility personnel from the time of waste delivery, through waste storage, processing and final transportation and disposal. As a minimum, the operations manual shall include:

1. Daily operations including a discussion of the timetable for development; waste types accepted or excluded; typical waste handling techniques; hours of operation; traffic routing; drainage and erosion control; windy, wet and cold weather operations; fire protection equipment; manpower; methods for handling of any unusual waste types; methods for vector, dust and odor control; daily cleanup; salvaging; record keeping; parking for visitors and employees; monitoring; backup equipment with names and telephone numbers where equipment may be obtained; and other

special design features. This information may be developed as a removable section to improve accessibility for the site operator.

2. The procedures that will be used to label individual waste containers, bulk containers or trailers with the date that the waste materials were received from off-site, and the procedures that will be used to demonstrate that the waste is treated within 15 days of receipt.

3. Site closing information consisting of a discussion of the anticipated sequence of events for site closing and discussion of those actions necessary to prepare the site for any anticipated post-closure use.

C. An emergency contingency plan that delineates procedures for responding to fire, explosions or any unplanned sudden or non-sudden releases of harmful constituents to the air, soil, or surface or ground water shall be submitted to the department as part of the Part B application. Before submission to the department it will be coordinated with the local police and fire departments, and the appropriate health care facility. The contingency plan shall contain:

1. A description of the actions facility personnel shall take in the event of various emergency situations;

2. A description of arrangements made with the local police and fire department that allow for immediate entry into the facility by their authorized representatives should the need arise, such as in the case of response personnel responding to an emergency situation; and

3. A list of names, addresses and phone numbers (office and home) of all persons qualified to act as an emergency coordinator for the facility. Where more than one person is listed, one shall be named as primary emergency coordinator and the other shall be listed in the order in which they will assume responsibility as alternates.

D. The applicant shall prepare and submit a detailed plan for closing any regulated medical waste management unit. Such a plan shall be prepared to reflect the actions required at any point in the life of the facility and at the time of closing the facility. The plan should reflect all steps necessary to isolate the facility from the environment or to remove all regulated medical waste and residue in the facility for proper treatment and to decontaminate the facility. The closure plan should reflect all actions necessary for facility abandonment or uses other than for regulated medical waste management.

**9 VAC 20-120-740. Effect of the permit.**

A. Each facility permitted to accept regulated medical waste requires periodic inspection and review of records and reports. Such requirements shall be set forth in the final permit issued by the department. The permit applicant, by accepting the permit, agrees to the specified periodic inspections.

B. Compliance with a valid permit and this chapter during its term constitutes compliance for purposes of enforcement, with the Virginia Waste Management Act. However, a permit may be modified, considered invalid, or terminated for cause as set forth in 9 VAC 20-120-690 D 7, D 8, and D 9.

C. A permit does not convey any property rights of any sort, or any exclusive privilege.

D. A permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of federal, Commonwealth or local law or regulations.

E. A permit may be transferred in accordance with the procedures in 9 VAC 20-120-690 D 6.

F. The permit may, consistent with 9 VAC 20-120-700, specify a schedule of compliance leading to compliance with this chapter.

1. Any schedules of compliance under this subsection or subsection G of this section shall require compliance as soon as possible.

2. Except as otherwise provided, if a permit establishes a schedule of compliance that exceeds one year from the date of permit issuance, the schedule shall set forth interim requirements and the dates for their achievement.

a. The time between interim dates shall not exceed one year;

b. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages of completion, the permit shall specify interim dates for the submission of reports of progress toward completion of the interim requirements and indicate a projected completion date.

3. The permit shall be written to require that no later than 14 calendar days following each interim date and the final date of compliance, a permittee shall notify the director, in writing, of his compliance or noncompliance with the interim or final requirements.

G. A permit applicant or permittee may cease conducting regulated activities (by receiving a terminal volume of regulated medical waste, and, in case of treatment or storage facilities, closing pursuant to applicable requirements, or, in case of disposal facilities, closing and conducting post-closure care pursuant to applicable requirements) rather than continue to operate and meet permit requirements as follows:

1. If the permittee decides to cease conducting regulated activities at a specified time for a permit that has already been issued:

a. The permit may be modified to contain a new or additional schedule leading to timely cessation of activities; or

b. The permittee shall cease conducting permitted activities before noncompliance with any interim or final compliance schedule requirement already specified in the permit.

2. If the decision to cease conducting regulated activities is made before the issuance of a permit whose terms will include the termination date, the permit shall contain a schedule leading to termination that will ensure timely compliance with applicable requirements.

3. If the permittee is undecided whether to cease conducting regulated activities, the director may issue or amend a permit to continue two schedules as follows:

a. Both schedules shall contain an identical interim deadline requiring a final decision on whether to cease conducting regulated activities no later than a date that ensures sufficient time to comply with applicable requirements in a timely manner if the decision is to continue conducting regulated activities;

b. One schedule shall lead to timely compliance with applicable requirements ;

c. The second schedule shall lead to cessation of regulated activities by a date that will ensure timely compliance with applicable requirements.

d. Each permit containing two schedules shall include a requirement that, after the permittee has made a final decision, he shall follow the schedule leading to compliance if the decision is to continue conducting regulated activities, and follow the schedule leading to termination if the decision is to cease conducting regulated activities.

4. The applicant's decisions to cease conducting regulated activities shall be evidenced by a firm public commitment satisfactory to the director, such as a resolution of the board of directors of a corporation.

**9 VAC 20-120-750. Closure care.**

A. An owner, operator or permittee intending to close a regulated medical waste management facility shall notify the department of the intention to do so as least 180 calendar days prior to the anticipated date of closing.

B. Closure shall occur in accord with an approved closure plan, which shall be submitted with the permit application documents and approved when the director acknowledges that the facility is considered to have a permit. The holder of the permit shall submit a proposed modified closure plan to the department for review and approval as such modifications become necessary during the life of the facility.

C. The department shall inspect all regulated medical waste management facilities that have been closed to determine if the closing is complete and adequate. It shall notify the owner of a closed facility, in writing, if the closure is satisfactory, and shall order necessary construction or such other steps as may be necessary to bring unsatisfactory sites into compliance with this chapter. Notification by the department that the closure is satisfactory does not relieve the operator of responsibility for corrective action to prevent or abate problems caused by the facility.

**9 VAC 20-120-760. Recording and reporting required of a permittee.**

A. A permit may specify:

1. Required monitoring, including type, intervals and frequency, sufficient to yield data that are representative of the monitored activity;

2. Requirements concerning the proper use, maintenance, and installation of monitoring equipment or methods, including biological monitoring methods when appropriate; and

3. Applicable reporting requirements based upon the impact of the regulated activity and as specified in this chapter.

B. A permittee shall be subject to the following whenever monitoring is required by the permit:

1. The permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation for at least three years from the sample or measurement date. The director may request that this period be extended.

2. Records of monitoring information shall include:

a. The date, exact place and time of sampling or measurements;

b. The individuals who performed the sampling or measurements;

c. The dates analyses were performed;

d. The individuals who performed the analyses;

e. The analytical techniques or methods used; and

f. The results of such analyses.

3. Monitoring results shall be maintained on file for inspection by the department.

C. A permittee shall be subject to the following reporting requirements:

1. Written notice of any planned physical alterations to the permitted facility, unless such items were included in the plans and specifications or operating plan approved by the department, shall be given to the director and approved before such alterations are to occur.

2. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of the permit, shall be submitted no later than 14 calendar days following each schedule date.

3. The permittee shall report to the department any noncompliance or unusual condition that may endanger health or environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within five calendar days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and, if the noncompliance has not been corrected, the anticipated time it is expected to continue. It shall also contain steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance.

D. Copies of all reports required by the permit, and records of all data used to complete the permit application must be retained by the permittee for at least three years from the date of the report or application. The director may request that this period be extended.

E. When the permittee becomes aware that he failed to submit any relevant facts or submitted incorrect information in a permit application or in any report to the director, he shall promptly submit such omitted facts or the correct information with an explanation.

**9 VAC 20-120-770. (Repealed.)**

**9 VAC 20-120-780. (Repealed.)**

**9 VAC 20-120-790. (Repealed.)**

**9 VAC 20-120-800. (Repealed.)**

**9 VAC 20-120-810. Amendment of permits.**

A. Temporary authorizations.

1. Upon request of the permittee, the director may, without prior public notice and comment, grant the permittee a temporary authorization in accordance with the requirements of this section. Temporary authorizations shall have a term of not more than 180 calendar days.

2. a. The permittee may request a temporary authorization for:

(1) Any substantive amendment meeting the criteria in subdivision 3 b (1) of this subsection; and

(2) Any major amendment that meets the criteria in subdivision 3 b (1) or (2) of this subsection; or that meets the criteria in subdivisions 3 b (3) and (4) of this subsection and provides improved management or treatment of a regulated medical waste already listed in the facility permit.

b. The temporary authorization request shall include:

(1) A description of the activities to be conducted under the temporary authorization;

(2) An explanation of why the temporary authorization is necessary; and

(3) Sufficient information to ensure compliance with standards in Part V (9 VAC 20-120-330 et seq.) or VI (9 VAC 20-120-400 et seq.) of this chapter.

c. The permittee shall send a notice about the temporary authorization request to all persons on the facility mailing list. This notification shall be made within seven calendar days of submission of the authorization request.

3. The director shall approve or deny the temporary authorization as quickly as is practical. To issue a temporary authorization, the director shall find:

a. The authorized activities are in compliance with the standards of Part V (9 VAC 20-120-330 et seq.), VII (9 VAC 20-120-520 et seq.), VIII (9 VAC 20-120-580 et seq.) or IX (9 VAC 20-120-630 et seq.) of this chapter.

b. The temporary authorization is necessary to achieve one of the following objectives before action is likely to be taken on an amendment request:

(1) To facilitate timely implementation of closure or corrective action activities;

(2) To prevent disruption of ongoing waste management activities;

(3) To enable the permittee to respond to sudden changes in the types or quantities of the wastes managed under the facility permit; or

(4) To facilitate other changes to protect human health and the environment.

4. A temporary authorization may be reissued for one additional term of up to 180 calendar days provided that the permittee has requested a substantive or a major permit amendment for the activity covered in the temporary authorization, and (i) the reissued temporary authorization constitutes the director's decision on a substantive permit amendment in accordance with the Solid Waste Management Regulations (9 VAC 20-80) or (ii) the director determines that the reissued temporary authorization involving a major permit amendment request is warranted to allow the authorized activities to continue while the amendment procedures of the Solid Waste Management Regulations (9 VAC 20-80) are conducted.

B. Newly defined or identified wastes. The permittee is authorized to continue to manage wastes defined or identified as regulated medical waste under Part III (9 VAC 20-120-80 et seq.) of this chapter if he:

1. Was in existence as a regulated medical waste management facility with respect to the newly defined or identified regulated medical waste on the effective date of the final rule defining or identifying the waste; and

2. (i) Is in compliance with the standards of Part V, VII, VIII or IX, as applicable, with respect to the new waste, submits a minor modification request on or before the date on which the waste becomes subject to the new requirements or (ii) is not in compliance with the standards of Part V or VI, as applicable, with respect to the new waste, but submits a complete permit amendment request within 180 calendar days after the effective date of the definition or identifying the waste.

C. The suitability of the facility location will not be considered at the time of permit amendment unless new information or standards indicate that an endangerment to human health or the environment exists that was unknown at the time of permit issuance.

APPENDIX 10.1. (Repealed.)

APPENDIX 10.4. (Repealed.)

**9VAC20-120-820. Duration of permits.**

Any permit for the management of regulated medical waste shall expire after 10 years of operation. Permits shall not be extended beyond the 10 year permit by permit transfer or modifications. At any time more than 180 calendar days prior to the expiration of the permit and no more than 480 calendar days prior to the expiration of the permit, the holder of a valid permit may request that the director renew the permit and submit all information known to permit holder that is changed or new since the original permit application and that has not been previously submitted to the director. A permit may be renewed for a period of 10 years of operation. Processing of the request will be in accordance with the following:

1. If the holder of a valid permit for a regulated medical waste management facility files with the director a request to renew the permit at least 180 calendar days prior to the expiration of that permit, the director will cause an audit to be conducted of the facility's past operation, its current condition and the records held by the department concerning the facility. Within 60 calendar days of receipt of a proper request, the director will report to the applicant the findings of the audit and those items of correction or information required before renewal will be considered. The director shall review the environmental compliance history of the permittee, material changes in key personnel, and technical limitations, standards, or regulations on which the original permit was based. If the director finds repeated material or substantial violations of the permittee or material changes in the permittee's key personnel would make continued operation of the facility not in the best interest of human health or the environment, the director shall deny the request for renewal of the permit. If the director finds the facilities to be insufficient to comply with regulations in effect at the time of the proposed renewal, the director shall deny the request for renewal. The director shall request any information from the permittee that is necessary to conduct the audit, and that is reasonably available to the permittee and substantive to the proposed renewal.

2. If the applicant files for renewal less than 180 calendar days prior to the expiration of the original permit or files an improper application the director shall deny the application for renewal. If an application for renewal has been denied for a facility, any further applications and submittals shall be identical to those for a new facility.

**9VAC20-120-830. Existing facilities qualifications.**

Owners and operators of existing and permitted infectious waste management facilities are not required to submit an application for a new permit at the time these amended regulations become effective. Existing permits will remain valid, except that conditions or waivers in existing permits that conflict with these amended regulations are void on the date six months from the effective date of these amended regulations. Operators of existing facilities are required to comply with these amended regulations within six months following their effective date and may comply at any time with any item contained in this chapter in lieu of a conflicting condition contained in an existing permit.

## Part XI
## Variances and Other Procedures

**9 VAC 20-120-840. General.**

Any person directly affected by this chapter may petition the director to grant a variance from any requirement of this chapter, subject to the provisions of this part. Any petition submitted to the director is also subject to the provisions of the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

The director will not accept any petition relating to:

1. Equivalent testing or analytical methods contained in EPA Publication SW-846;

2. Definitions of regulated medical waste contained in Part III (9 VAC 20-120-80 et seq.) of this chapter; and

3. A change in the regulatory requirements that the petitioner is currently violating until such time as the violation has been resolved through the enforcement process.

**9VAC20-120-850. Application and conditions.**

The director may grant a variance from any regulation contained in Parts IV through X to a petitioner if the petitioner demonstrates to the satisfaction of the director that:

1.

a. Strict application of the regulation to the facility will result in undue hardship that is caused by the petitioner's particular situation, or

b. Technical conditions exist that make a strict application of the regulation difficult to achieve, and

c. The alternate design or operation will result in a facility that is equally protective of the human health and the environment as that provided for in the regulations; and

2. Granting the variance will not result in an unreasonable risk to the public health or the environment.

**9VAC20-120-860. Effects of the decisions.**

A. When the director renders a decision under this section in accordance with the procedures contained here, he may:

1. Deny the petition;

2. Grant the variance as requested; or

3. Grant a modified or partial variance.

B. When a modified variance is granted, the director may:

1. Specify the termination date of the variance;

2. Include a schedule for:

a. Compliance, including increments of progress, by the facility with each requirement of the variance; and

b. Implementation by the facility of such control measures as the director finds necessary in order that the variance may be granted.

**9VAC20-120-870. Submission of petition.**

A. All petitions submitted to the director shall include:

1. The petitioner's name and address;

2. A statement of petitioner's interest in the proposed action;

3. A description of desired action and a citation to the regulation from which a variance is requested;

4. A description of need and justification for the proposed action;

5. The duration of the variance, if applicable;

6. The potential impact of the variance on public health or the environment;

7. Other information believed by the petitioner to be pertinent; and

8. The following statements signed by the petitioner or his authorized representative:

"I certify that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

B. In addition to the general information required of all petitioners under this article:

1. To be successful the petitioner shall address the applicable standards and criteria.

2. The petitioner shall provide an explanation of the petitioner's particular situation that prevents the facility from achieving compliance with the cited regulation.

3. The petitioner shall provide other information as may be required by the department.

**9 VAC 20-120-880. Petition processing.**

A. After receiving a petition that includes the information required in 9 VAC 20-120-870, the director will determine whether the information received is sufficient to render the decision. If the information is deemed to be insufficient, the director will specify additional information needed and request that it be furnished.

B. The petitioner may submit the additional information requested, or may attempt to show that no reasonable basis exists for the request for additional information. If the director agrees that no reasonable basis exists for the request for additional information, he will act in accordance with subsection C of this section. If the director continues to believe that a reasonable basis exists to require the submission of such information, he will proceed with the denial action in accordance with the Virginia Administrative Process Act (VAPA).

C. After the petition is deemed complete:

1. The director will make a tentative decision to grant or deny the petition.

2. In case that petition may be tentatively denied, the director will offer the petitioner the opportunity to withdraw the petition, submit additional information, or request the director to proceed with the evaluation.

3. Unless the petition is withdrawn, the director will issue a draft notice tentatively granting or denying the application. Notification of this tentative decision will be provided by newspaper advertisement in the locality where the petitioner is located. The director will accept comment on the tentative decision for 30 calendar days.

4. Upon a written request of any interested person, the director may, at his discretion, hold an informal fact finding meeting described in § 2.2-4011 of the Virginia Administrative Process Act. A person requesting a meeting shall state the issues to be raised and explain why written comments would not suffice to communicate the person's views. The director may in any case decide on his own motion to hold such a meeting.

5. After evaluating all public comments the director will, within 15 calendar days after the expiration of the comment period:

a. Notify the petitioner of the final decision; and

b. Notify all persons who commented on the tentative decision or publish it in a newspaper having circulation in the locality.

**9VAC20-120-890. Petition resolution.**

A. In the case of a denial, the petitioner has a right to request a formal hearing to challenge the rejection.

B. If the director grants a variance request, the notice to the petitioner shall provide that the variance may be terminated upon a finding by the director that the petitioner has failed to comply with any variance requirements

**9VAC20-120-900. General.**

The requirements for alternate treatment methods contained in Part IX allow, at subdivision 2 d of 9VAC20-120-640, that new or innovative treatment technologies can be approved for permitting if the director reviews the process and determines that it provides treatment in keeping with this chapter and protects public health and the environment, and if the director establishes appropriate conditions for their siting, design, and operation. This article establishes the criteria, protocols, procedures, and processes to be used to petition the director for review and to demonstrate the suitability of the proposed process for the treatment of regulated medical waste.

**9VAC20-120-910. Criteria for microbial inactivation.**

A. Inactivation is required to be demonstrated of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log10 reduction or greater; a 6 Log10 reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction).

B. Inactivation is required to be demonstrated of B. stearothermophilus spores or B. subtilis spores at a 4 Log10 reduction or greater; a 4 Log10 reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction).

**9VAC20-120-920. Representative of biological indicators.**

A. One or more representative microorganisms from each microbial group shall be used in treatment efficacy evaluation.

1. Vegetative Bacteria.

- Staphylococcus aureus (ATCC 6538)

- Pseudomonas aeruginosa (ATCC 15442)

2. Fungi.

- Candida albicans (ATCC 18804)

- Penicillium chrysogenum (ATCC 24791)

- Aspergillus niger

3. Viruses.

- Polio 2 or Polio 3

- MS-2 Bacteriophage (ATCC 15597-B1)

4. Parasites.

- Cryptosporidium spp. oocysts

- Giardia spp. cysts

5. Mycobacteria.

- Mycobacterium terrae

- Mycobacterium phlei

- Mycobacterium bovis (BCG) (ATCC 35743)

B. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems.

1. B. stearothermophilus (ATCC 7953)

2. B. subtilis (ATCC 19659)

**9VAC20-120-930. Quantification of microbial inactivation.**

A. Microbial inactivation ("kill") efficacy is equated to "Log10 Kill," which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is equated as:

Log10 Kill = Log10 I(cfu/g) %68 Log10 R(cfu/g) where:

Log10Kill is equivalent to the term Log10 reduction.

"I" is the number of viable test microorganisms introduced into the treatment unit.

"R" is the number of viable test microorganisms recovered after treatment.

"cfu/g" are colony forming units per gram of waste solids.

B. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration can be used to demonstrate treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of treatment efficacy requires a two step approach: Step 1, "Control"; Step 2, "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

1. Step 1.

a. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.

b. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals).

c. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

d. Plate recovered microorganism suspensions to quantify microbial recovery. (The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the microbial inactivation agent).

e. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction as specified in 9VAC20-120-910 (i.e., a 6 Log10 reduction for vegetative microorganisms or a 4 Log10 reduction for bacterial spores). This can be defined by the following equation:

Log10RC = Log10IC %68 Log10NR

where: Log10RC is greater than or equal to 6 for vegetative microorganisms and is greater than or equal to 4 for bacterial spores and where:

Log10RC is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) recovered in the nontreated processed waste residue.

Log10IC is the number of viable "Control' microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit.

Log10NR is the number of "Control" microorganisms (in colony forming units per gram of waste solids) that were not recovered after processing. Log10NR represents an accountability fad-or for microbial loss.

2. Step 2.

a. Use microbial cultures of the same concentration as in Step 1.

b. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the microbial inactivation agent.

c. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

d. Plate recovered microorganism suspensions to quantify microbial recovery.

e. From data collected from Step 1 and Step 2, the level of microbial inactivation (i.e., "Log10 Kill") is calculated by employing the following equation:

Log10Kill = Log10IT %68 Log10NR %68 Log10RT, where:

Log10Kill is equivalent to the term Log10 reduction.

Log10IT is the number of viable "Test" microorganisms-(in colony forming units per gram of waste solids) introduced into the treatment unit. Log10IT = Log10IC.

Log10NR is the number of "Control microorganisms (in colony forming units per gram of waste solids) that were not recovered after processing.

Log10RT is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.

**9VAC20-120-940. Efficacy testing protocols.**

A. Methodology employed to determine treatment efficacy of the technology will need to assure required microbial inactivation and assure the protocols are congruent with the treatment method. Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures such as those found in Test Methods for Evaluating Solid Waste, Physical/Chemical Methods and Standard Methods for the Examination of Water and Waste Water.

B. The department shall prescribe those types and compositions of medical wastes that present the most challenge to treatment effectiveness under normal operating conditions of the equipment reviewed.

C. Dependent on the treatment process and treatment efficacy mechanisms utilized, protocols evaluating medical waste treatment systems shall specifically delineate or incorporate, as applicable:

1. Waste compositions that typify actual waste to be processed;

2. Waste types that provide a challenge to the treatment process;

3. Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume);

4. Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process;

5. Assurances of inoculum traceability, purity, viability and concentration;

6. Dilution and neutralization methods that do not affect microorganism viability;

7. Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples/test, number of colony forming units/plate); and

8. Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times).

**9VAC20-120-950. Technology approval process.**

A. To initiate the technology review process the petitioner shall complete and submit the "Petition For Evaluation and Approval of Regulated Medical Waste Treatment Technology Part A: General Information" to the department. The petitioner shall:

1. Provide a detailed description of the medical waste treatment equipment to be tested including manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, pressure, temperatures, chemical concentrations, irradiation doses, feed rates, and waste load composition;

2. Provide documentation demonstrating the treatment method meets microbial inactivation criteria and required testing protocols including a detailed description of the test procedures and calculations used in fulfilling required performance standards verifying treatment efficacy, of user verification methodology, and of microbial culturing protocols that ensure traceability, purity and concentration;

3. Provide information on available parametric controls, verifying treatment efficacy and ensuring operator non-interference;

4. Provide documentation of applicable emission controls for suspected emissions;

5. Provide information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling;

6. Provide documentation providing occupational safety and health assurance; and

7. Provide information on energy efficiency and other potential benefits the treatment technology has to offer to the environment.

B. The petitioner shall demonstrate that all required surrogate pathogens and resistant bacterial endospores are inactivated to criteria specified in 9VAC20-120-910 and 9VAC20-120-930 under the representative challenge waste load compositions.

C. The petitioner shall develop and demonstrate that site approval and user verification testing protocols are workable and valid.

D. The petitioner shall demonstrate where technically practical, the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

E. The petitioner shall demonstrate evidence of U.S. EPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

F. Upon completion of items contained in 9VAC20-120-910 through 9VAC20-120-950, the technology approval that results is granted only under the conditions specified in the manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, temperatures, pressure, chemical concentrations, irradiation doses, feed rates, and waste load composition. Any significant revisions to these equipment and operating conditions, as warranted relevant to the department, will require reapplication for approval to the department.

**9VAC20-120-960. Site approval process.**

A. To fulfill treatment efficacy and information requirements for site approval, the equipment user shall:

1. Demonstrate that the equipment cited is the same equipment and process approved by the department as specified in 9VAC20-120-950.

2. Demonstrate that required resistant bacterial endospores are inactivated as specified in 9VAC20-120-910 B criteria under typical waste load and department specified challenge compositions;

3. Verify that user verification protocols adequately demonstrate treatment effectiveness; and

4. Verify the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

B. The site facility shall provide a written operations plan that includes:

1. The names or positions of the equipment operators;

2. The waste types or categories to be treated;

3. Waste segregation procedures required;

4. Wastes types prohibited for treatment;

5. Equipment operation parameters;

6. Treatment efficacy monitoring procedures;

7. Personal protective equipment requirements;

8. Emergency response plans; and

9. Operator training requirements.

C. The site facility shall submit to the department for their review:

1. Equipment model number and serial number;

2. Equipment specification and operations manual;

3. A copy of the facility's written plan; and

4. Certification documentation of operator training.

D. As a condition of site approval, the department shall have a right to inspect the facility and the right to revoke site approval if health and safety violations are discovered, if permit conditions are not being fulfilled, or if the facility is not adhering to its written plan.

E. Any modifications to the medical waste treatment unit may require re-approval by the director and may involve further efficacy testing.

**9VAC20-120-970. User verification.**

A. To verify that the medical waste treatment unit is functioning properly and that performance standards are achieved, the petitioner shall:

1. Demonstrate that required resistant bacterial endospores are inactivated to criteria as specified in 9VAC20-120-910 B under standard operating procedures using protocols that have previously been approved by the department as specified under 9VAC20-120-950 and 9VAC20-120-960;

2. Establish a frequency of biological monitoring; and

3. Document and record all biological indicator and parametric monitoring data.

B. To document treatment efficacy for steam sterilizers and autoclaves, the equipment operator shall:

1. Adopt standard written operating procedures that denote:

a. Sterilization cycle time, temperature, pressure

b. Types of waste acceptable

c. Types of containers and closures acceptable

d. Loading patterns or quantity limitations;

2. Document times/temperatures for each complete sterilization cycle;

3. Use time-temperature sensitive indicators to visually denote the waste has been decontaminated;

4. Use biological indicators placed in the waste load (or simulated load) periodically to verify conditions meet microbial inactivation requirements as specified in 9VAC20-120-910 B; and

5. Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results.

**9VAC20-120-980. Small medical waste treatment devices.**

A. All small medical waste treatment devices shall fulfill the requirements necessary for technology approval and shall meet the treatment efficacy requirements as defined in 9VAC20-120-910.

B. Technology and siting approval are the responsibility of the petitioner. The petitioner shall provide to the department:

1. All information required for technology approval as defined in 9VAC20-120-950;

2. All information required of site approval for a typical site for which the equipment is designed as defined in 9VAC20-120-960; and

3. All materials and documents required of the user to ensure proper use, safety, and effective treatment. These materials and documents would include:

a. An operations and maintenance manual;

b. Information on proper use and potential misuse;

c. Treatment efficacy testing instructions;

d. Training/education manual; and

e. Available service agreements/programs.

C. The manufacturer (vendor) shall furnish the user of the treatment device:

1. An operations and maintenance manual;

2. Information on proper use and potential misuse;

3. Treatment efficacy testing instructions;

4. Training/education manual; and

5. Available service agreements/programs.

D. Upon the installation of the treatment device, the manufacturer shall compile a record of the buyer, the location, and the results of onsite challenge testing at time of purchase. This information shall be submitted annually to the department by the petitioner as the notification record of site registrations of equipment installed that previous year.

**9VAC20-120-990. Waste residue disposal.**

A. Information on the characteristics of all waste residues (liquids and solids), and the mechanisms and models of their disposal shall be provided by the petitioner on the "Evaluation of Medical Waste Treatment Technology: Information Request Form." This information will include:

1. Description of residues (i.e., liquid, solid, shredded, hazardous constituents);

2. Waste designation (i.e. hazardous, special, general);

3. Disposal mechanism (i.e. landfilling, incineration, recycling); and

4. Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort).

B. Information on waste residue disposal shall be provided by the user facility as required under site approval (9VAC20-120-960). This information shall include:

1. All information requested in 9VAC20-120-1000 A;

2. The site of disposal (name and address);

3. The mechanism of disposal (i.e. landfilling or incineration); and

4. The amounts of residues anticipated to be disposed (e.g., volume and weight per week).

C. If residues are to be recycled the following information shall be provided by the user facility as required under site approval (9VAC20-120-960). This information shall include:

1. The types of waste residue to be recycled;

2. The amounts of waste residue to be recycled;

3. The percentage of the total waste and waste residue to be recycled;

4. The recycling mechanism used; and

5. The name and location of the recycler.

D. Previously untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed as untreated medical waste.

E. Prototypical equipment testing using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended surrogate pathogens can be disposed as general solid wastes after verification of treatment effectiveness.

F. All liquid and solid waste residues will be disposed of in accordance with applicable state and local regulations.

**9VAC20-120-1000. Operator training.**

A. To assure proper operation of the treatment process, the manufacturer (vendor) shall provide to the user as part of the treatment equipment purchase an operator training program that will include:

1. A description of all mechanical equipment, instrumentation, and power controls;

2. A description of system's operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal;

3. A description of all parametric controls, their appropriate settings as correlated with biological indicators, and calibration requirements ;

4. A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials);

5. A description of personal protective equipment requirements for routine, abnormal, and emergency operations; and

6. A description of all potential occupational safety and health risks posed by the equipment and its use.

B. The facility shall additionally develop a written treatment equipment operations plan that will include:

1. Responsibility delegation for safe and effective equipment operation to operating personnel;

2. A description of operating parameters that must be monitored to ensure effective treatment;

3. A description of all process monitoring instrumentation and established ranges for all operating parameters;

4. A description of the methods required to ensure process monitoring instrumentation is operating properly; and

5. A description of methods and schedules for periodic calibration of process monitoring instrumentation.

C. The facility shall document and keep on record copies of all training for at least three years.

FORMS

Solid Waste Management Facility Permit Applicant's Disclosure Statement (Cover Sheet), DEQ Form DISC-01 (rev. 11/01).

Solid Waste Management Facility Permit Applicant's Disclosure Statement (Key Personnel), DEQ Form DISC-02 (rev. 11/01).

Request for Local Government Certification, DEQ Form CERT-01 (rev. 11/01).

Treatment Process Petition, DEQ Form RMWTP-01 (rev. 11/01).